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Integration of Pharmacists into Patient-Centered Medical Homes (PCMHs) in Federally Qualified Health Centers in Texas

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Integration of Pharmacists into Patient-Centered Medical Homes (PCMHs) in Federally Qualified Health Centers in Texas

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Dedication

I would like to dedicate this thesis to my dearest mother and father, for their unconditional love and support, and their encouragement for me to pursue pharmacy and this master's degree. Also, to my aunt and uncles who passed away, for being inspiring guardians.

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Abstract

Integration of Pharmacists into Patient-Centered Medical Homes (PCMHs) in Federally Qualified Health Centers in Texas

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The Patient-Centered Medical Home (PCMH) model of care is based on coordinated team care that provides personalized and sustainable medical interventions. Meanwhile, the heavy burden imposed by diabetes to the health care system is rising and this burden is even higher among underserved populations. Multidisciplinary team care has been shown to improve diabetes management. However, pharmacists' involvement in PCMHs varies among settings and few studies have described their integration. This qualitative study describes the pharmacy services integration in PCMHs as adopted by Federally Qualified Health Centers (FQHC) in Austin, Texas. All four clinics in this study have pharmacists who are integrated in the medical team, and who provide pharmacy services according to a collaborative practice agreement. Since early 2013, three of the PCMH group clinics instituted co-visits, where the patient sees both the physician and the pharmacist on the same day.

Separate interview sessions were conducted independently with the three PCMH FQHCs and one usual care FQHC to describe the implementation of diabetes-related pharmacy services. A semi-structured interview guide was developed beforehand and the interviews were audio recorded. Qualitative content analysis was conducted, independently, by two researchers to categorize pharmacists' responses. Discrepancies were resolved through discussions.

Clinical pharmacists in the FQHCs work collaboratively with physicians and provide services as guided by the collaborative practice agreement. On co-visit days (PCMH clinics only), the pharmacists may see the patients before or after physician consultation. This co-visit arrangement allows for more collaboration and more efficient communication with physicians. Payment that recognizes value of PCMH is one principle of PCMH that is not fully realized in the study sites.

In conclusion, the structure of PCMH and the integration of pharmacy services employed by the FQHCs incorporated the criteria of the Joint Principles of PCMH, namely, personal physician, physician-directed medical practice, whole person orientation, coordinated and/or integrated care, quality and safety, and enhanced access. Effective integration of pharmacist in the PCMH demonstrates that the workflow is established according to the needs of organization and the PCMH caters to alleviate the burden of primary care activities in an underserved patient population.

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CHAPTER 1: INTRODUCTION AND LITERATURE REVIEW

1.1 INTRODUCTION AND BACKGROUND

In the United States, 80% of adults have medications as part of their treatment plan and about 30% of the population are taking at least 5 different drugs.[1] Medication management is therefore important to ensure safety and efficacy of medications. Medication-related problems and medication errors are costly, and they account for more than USD 200 billion per year with continuous annual increments.[2,3] Patients may receive their prescription and over-the-counter medications as well as supplements from different sources, which may lead to drug interactions and adverse events. The absence of a comprehensive medication list and the lack of communication between health care professionals can compromise safety and quality of care.[4]

Meanwhile, the heavy burden imposed by diabetes to the health care system is rising worldwide and in the US.[5,6] The latest data estimated that about 9.3% of the population in the US have diabetes and it is in the top ten leading causes of death in the country.[7] The burden of diabetes is even higher among underserved populations, predominantly minorities, low-income and uninsured patients.[8–10] The disparity in health care access and diabetes outcomes has been linked to lower education levels and cultural barriers. Multidisciplinary team care that provides patient-centered services have been shown to improve the management of diabetes for underserved patients.[11–13]

The overall state of poor medication management and challenges in diabetes management with disadvantaged populations are issues that should be urgently addressed. Pharmacist involvement with medication management in a team-based approach has been recommended for these challenges and improved outcomes, such as decreased HbA1c, have been reported by models of care that have integrated pharmacists.[14–16] Further, a report of Priority Areas for National Action: Transforming

Health Care Quality revealed that the collective expertise of a primary care team, which included pharmacists, is required to enhance the quality of health care.[17] Additionally, emphasis has been placed on the need to include patients in the decision-making process to empower them and to promote active participation in their own medication management.[18]

The patient-centered medical home (PCMH) concept corresponds to these needs of the health care system. The PCMH model of care is based on coordinated team care that provides personalized and sustainable medical interventions, as opposed to episodic care that can oftentimes be reactive as opposed to proactive.[19,20] PCMH aims to provide comprehensive primary care that ultimately improves the quality and decreases the cost of health care services.[19,21] Although the concept of PCMH has existed since 1967, there has been a renewed interest prompted by the Affordable Care Act (ACA), and Accountable Care Organizations (ACOs), both of which promote integration within health care teams.[19,21,22]

In the original model of PCMHs, pharmacists were not specifically named and even in the most current models, pharmacists are seldom mentioned in medical home discussions. However, there is growing recognition of shared responsibilities among health care team members and justification for pharmacist involvement as members of PCMHs has been reported in the literature.[23,24] Pharmacists' roles include comprehensive medication management or the commonly interchanged term, medication therapy management (MTM). The provision of MTM by pharmacists is an important component of a successful PCMH, which is anchored in team-based care.[14] Besides that, pharmacists' proficiency in providing medication reconciliation, actively managing medication-related problems, developing individualized care plans, making interventions, providing referrals, and following-up to evaluate outcomes is parallel with the PCMH's concept of continuity of care.[14,18]

Pharmacists' involvement in PCMHs vary among settings and few studies have described their integration into these models of care. One guiding principle is that pharmacy services should be integrated according to the needs of the specific PCMH.[25] Published studies describing pharmacist involvement typically focus on structure (e.g., employment, responsibilities, workflow) and outcomes. Regarding employment, pharmacists can be hired by the organization directly or they can contract out their clinical services to provide MTM. The latter provides more flexibility for patients in terms of when and where they receive services.[24,25] Responsibilities are typically outlined in collaborative practice agreements between the physician and the pharmacist. These agreements delegate authority to the pharmacist to provide agreed upon patient care services (e.g., adjustment of dosage regimens and ordering laboratory procedures).[23] As of 2010, approximately 46 states have pharmacy collaborative practice acts.[23] These state policies facilitate and support more pharmacist involvement in patient care activities.

In addition to the structure components of employment and responsibilities, workflow should also be tailored to the specific institution. One aspect of workflow is the timing of pharmacist visits, which may occur before, during, or after the primary care provider visit (i.e., on the same day) or on a separate day. Another aspect of workflow is the criteria used to determine the need for clinical pharmacist visits. Some PCMHs may schedule a clinical pharmacist visit for every patient or for selected patients that meet specific criteria, such as physician referral only or based on specific predetermined criteria (e.g. HbA1c more than 9%, more than 5 chronic medications).[24] The workflow should be agreed on to ensure effective communication among the health care team and the patient.[25]

Apart from the PCMH structure, as described above, the second main PCMH focus area in the literature is outcomes. However, outcomes regarding PCMH models are mixed and more evidence related to clinical and economic outcomes is needed.[26,27] A recent study reported positive outcomes from a PCMH, particularly with enhanced

prevention, chronic disease management, patient satisfaction and cost reduction.[28] Other studies however, found no significant improvements in hospitalizations and emergency department (ED) visits.[29,30] Models of care that involved pharmacists have been shown to improve outcomes of various diseases, such as hypertension, diabetes, asthma, renal disease and cardiovascular disease.[4,23,31] Specifically, regarding PCMHs studies that focused on diabetes, early demonstration projects revealed encouraging evidence with improvements in HbA1c, blood pressure, LDL cholesterol, hospitalizations, readmissions and emergency room visits.[32] In a review of pharmacists' interventions and diabetes outcomes, the greatest improvements in HbA1c were observed when pharmacists were incorporated in collaborative practice models.[33]

Pharmacists integrated in PCMHs are valuable resources to improve diabetes management, particularly with quality of care and safety of medications, both of which can translate into cost savings. Although the literature on PCMHs is growing, few studies have described the structure of medical homes, or the responsibilities and workflow of the pharmacists in these entities. Similarly, studies that report clinical, utilization and economic outcomes are scarce, and when available, results are mixed. This suggests a need for more research in this area to provide a better understanding of the impact of pharmacists on diabetes outcomes in underserved populations, who generally have poorer outcomes.

Therefore, the goal of this study is to describe the implementation of pharmacists-integrated PCMH in federally qualified health centers (FQHCs), which primarily provide care to underserved patients. Descriptions on successful application of the PCMH concepts will help with the refinement of the model, and more evidence of the value of such practices may support future development PCMHs.

1.2 LITERATURE REVIEW

New models of care are growing and development in this area, including integration of pharmacists in team-based management, has been increasingly documented in the literature. This literature review examines several concepts applied by integrated models of care, with specific attention to the principles of patient-centered medical homes (PCMHs). The roles and responsibilities of pharmacists are described and the impact, outcomes, challenges and barriers of pharmacists' integration in these structures are discussed. The review also encompasses the burden of diabetes mellitus in underserved populations, who could potentially benefit from the pharmacist services in PCMHs.

1.2.1 Current Trends in Integrated Models of Care

Health care in the US has generally been provided through the fee-for-service system and years of evolvement have resulted in a complex structure that is commonly described as expensive with poor quality of care. The system has been described as fragmented with providers being incentivized by a payment structure that rewards volume, growth and intensity.[22,34] The traditional approach provides direct access to individual health care providers but has discouraged active patient involvement in the management of their health condition, and it has compromised communication across different providers in chronic care.[35] With these issues being identified in the last decade, there have been initiatives to promote integrated care systems to address weaknesses of the existing system. The general idea of integrated care is that physicians, specialists, and hospitals coordinate patient care by sharing patient information and preventing duplicate or unnecessary tests and treatments.[22,36] Since medical care is delivered via interdependent arrangements between different health care providers that complement each other, collaboration between various parts of the system is vital to the effective and efficient delivery of health care services.[37]

Integrated care is one method to organize health care and it has various delivery mechanisms. The World Health Organization defined integration as "The management and delivery of health services so that clients receive a continuum of preventive and curative services, according to their needs over time and across different levels of the health system."[38] Integrated care has also been defined from the context of a "bottom-up" approach, i.e., one that is structured according to the needs of patients. Other definitions of integrated care include: a package that delivers multiple services under one roof, services that extend over time to provide continuity of care, vertical integration of health care services which is overseen by a manager, or a team with integrated policy and management.[38] When administered appropriately, integrated care can lead to improvement in quality, accessibility, safety and cost-effectiveness of health care.[37,39] In summary, the traditional practice of medicine where the physician is the sole decision maker is changing to a pragmatic approach that involves patients' concerns and participation in the health care decision-making process.[38]

The concept of integrated and patient-centered care has been growing and the pursuit of identifying criteria for successful models is ongoing. Enthoven A.C (2009) reported that a successful integrated delivery system should encompass the following principles: shared organizational commitments, physician leadership, patient-centeredness with a focus on population health, coordinated care and information, appropriate financial incentives, evidence-based medicine, efficient electronic health records, appropriate physician-patient ratio, and continuous innovation.[40] Early favorable outcomes from pioneer models of integrated care such as Kaiser Permanente and Cleveland Clinic have also prompted the recent health care reform efforts to encourage initiatives such as Accountable Care Organizations (ACOs), which emphasize the value of integrated care.[22]

1.2.1.1 Accountable Care Organizations (ACOs)

Accountable Care Organizations were introduced in 2010 along with the Affordable Care Act (ACA) with the aim to encourage providers, across different settings such as physician offices, hospitals and long-term care facilities, to work together with a focus on patients' needs. The ultimate goal of ACOs was to achieve high quality care with lower costs by implementing a continuum of care.[36] Physicians have long worked in coordinated care in closed system Health Maintenance Organizations (HMOs), where the health plan and providers serve only their members.[22,34] ACOs extend this concept with a lift of the restricted network in HMOs to allow patients to receive care from ACOs or non-ACO providers.[22,34,36]

To incentivize the provision of high quality care at lower costs, the Centers for Medicare & Medicaid Services (CMS) provide ACOs with a Shared Savings Program. This program measures the performance and targets of the patient population under the ACO, and directs savings from improved outcomes to the providers.[22,36] With the financial incentives, ACOs are motivated to share information as a large integrated network and to emphasize preventive care as accountabilities for patients are shouldered upon the ACOs.[41] A variety of providers can be part of ACOs – from large integrated or multispecialty group practices such as Kaiser Permanente or Cleveland Clinic that are readily incorporated as ACOs, to hospital-based systems and small independent physician practices.[41,42] Two examples of successful integrated health care systems, Kaiser Permanente and Cleveland Clinic, are highlighted below.

1.2.1.2 Kaiser Permanente

Founded in 1945, Kaiser Permanente has grown to be the largest nonprofit integrated health care delivery system in the United States.[43,44] As a part of Kaiser Permanente, Kaiser Foundation Health Plans serves as the payer, and it uses the capitation method. This enables Kaiser to have both roles of payer and provider (including laboratory and pharmacy), which can enable them to better account for the

clinical care, quality improvement and resource management throughout the system.[40,44,45] The organization generally provides multidisciplinary services under one roof, with doctors from primary, secondary and tertiary care settings sharing the budget and responsibilities for all care.[44,46,47] The system is stratified to provide appropriate care according to the complexity of the services needed, with the philosophy that a strong primary care is the base for efficient patient management.[44]

Kaiser is well recognized for its electronic medical record system, which promotes team work between providers, facilitates communication with the patients and monitors quality performance. Some of the latest innovations include evidence-based electronic prescribing and population disease registries that can track patients with chronic conditions with the purpose of early detection and prevention.[44,48] Another driver of collaboration and coordination in Kaiser is the culture of internal transparency, which promotes sharing of information and peer reviews among the physicians. Physicians also have high autonomy in both clinical protocols and management of the health plan.[44]

An interesting comparison between Kaiser Permanente and the National Health Service (NHS) in the UK revealed that Kaiser achieved better performance on the following: more comprehensive and convenient primary care services, faster access to specialist services and hospital admissions, and shorter length of acute bed days.[49] Examples of other positive population health outcomes from Kaiser programs include: reduction in relative risk of death from cardiac events, improvement in the blood pressure and blood glucose control, and reduction of hospitalization rates for myocardial infarction.[44]

1.2.1.3 The Cleveland Clinic

Started in 1921, Cleveland Clinic is a another example of a nonprofit multispecialty academic medical center that integrates clinical and hospital care with research and education.[50] Based in Cleveland, Ohio, the network has expanded globally to

more than 70 countries.[51] The physician-led Cleveland Clinic model emphasizes patients' needs and long-term patient-doctor relationships.[50–52]

Among their success stories are: same day access, reduction in wait time for new appointments to 7 days and a patient-tracking GPS system that reduced 20% of office visit wait times.[52,53] Doctors and nurses have access to the patients' electronic medical records (EMRs) regardless of the patients' location in tertiary or primary care. Interestingly, there is also Critical Care Transport, which consists of air and land transportation equipped with travelling medical personnel on standby to transfer patients from different countries and states to receive advanced care.[52]

Cleveland Clinic has been commended regarding their transparency efforts. Clinical outcomes from the institution such as mortality, complication rates and patient satisfaction are published annually.[51,52,54] Real-time, transparent snap-shots of key performance metrics are made available to inform and align providers, and to ensure protocols are applied consistently throughout the system.[52] Cost is also tracked and analyses are conducted to enhance cost-effectiveness. Examples of these efforts include: replacement of a $400 staple with a $5 stitch for suturing, and improvement of sterile conditions to reduce catheter-related and urinary tract infections.[55] Research and education are also integral to the clinic and findings are shared to inform the health care community.[51]

Similarities of the successful models discussed include seamless systems that mutually depend on different specialties, continuous innovation and having a strong primary care. The concepts from these exemplary systems are also shared by primary care institutions – that are commonly called medical homes. These types of health care models are further described in the following sections.

1.2.2 Concept of Medical Home in Primary Care

Often interchanged with terms such as advanced medical home, advanced primary care practice, patient-centered medical home or health home, the concept of medical home refers not to a physical structure but an approach for providing comprehensive and coordinated primary care.[21,24] The medical home model has been stressed by policy makers in recent years as one of the methods to address challenges of the US health care system, which include poor access and suboptimal primary care.[56,57]

Among the reasons for the suboptimal primary care system is that careers in primary care, such as in general internal medicine and family medicine, are becoming less popular among medical graduates. Consequently, there is a shortage of primary care physicians, who are faced with challenges in providing quality care for the patients. The concept of a medical home has been proposed to overcome this issue as many physicians' responsibilities can be delegated to other health care practitioners such as nurses, medical assistants and pharmacists through an integrated team structure.[56–58] Additionally, evidence supports that access to primary care services improves health outcomes, regardless of the supply of primary care physicians.[59]

The medical home concept, which is comprised of primary care management, person-centered, problem-solving, comprehensive, community, and holistic approaches is also advocated by health care systems around the world including Australia, Canada and Europe.[60–62] In the US, pediatricians pioneered the medical home concept in 1967 with the idea of having a centralized medical record of children with special health care needs.[19,21] Later in 2007, four primary care physician societies developed the Joint Principles of the Patient-Centered Medical Home, which became the main guide for further development of the model, as discussed next.[21]

1.2.2.1 Patient-Centered Medical Home (PCMH)

PCMH is a coordinated care model focused on patient needs through continuous patient-physician relationships, as opposed to the conventional episodic care.[19,20] The core of the system is a team of primary care providers, from nurses to frontline staff who are led by clinicians, complemented by evidence-based medicine and information technology to provide health care with optimal quality and safety.[19,21] While the ACO model targets accountability and alignment of incentives for providers, the PCMH model focuses on the primary care structure, as both are important building blocks for health delivery system reforms.[63]

According to the Joint Principles of the Patient-Centered Medical Home,[21] the pillars of PCMH are:

1) **Personal physician** who provides continuous care to each patient
2) **Physician directed medical practice** that leads a team that is responsible for the patients
3) **Whole person orientation** where the physician should provide care for all patients' health care needs or make referrals when necessary
4) **Care is coordinated and/or integrated** across the complex health care system from hospitals and nursing homes, to the patient's community
5) **Quality and safety** through patient-centered partnerships, evidence-based medicine, accountability, patients' participation in decision-making, optimal use of information technology, and quality recognition process
6) **Enhanced access** such as open scheduling, expanded hours and innovative communication means
7) **Payment** that recognizes the added value from PCMH

To elaborate on these principles, patient-centeredness is being respectful of patients' needs and preferences, ensuring understanding and involving patients' participation in the care plan and self-management.[64] Together with the long-term

relationship with a primary care physician, the patient's care is personalized.[20] Next, effective team-based care allows each non-physician staff member to maximize their professional skill sets to complement each other.[64,65] Cross-training of staff helps with the ability of the practices to overcome staff absences and turnover.[64] As a consequence, physicians can focus on the management of complex medical conditions.[65] Discernibly, effective communication among team members and outside providers is critical for coordination as poor communication may lead to duplication of services, as well as with unnecessary anxiety and financial costs for the patients and caregivers.[64,65]

For care coordination, health information technology (HIT) is central to synchronize patient records, referrals and to provide transitions of care (e.g., from hospitalization to outpatient follow up).[48,65] Population health management is feasible with the assistance from electronic patient registries to shortlist patients according to the targeted conditions as determined by the team.[52,65] Systematic approaches to monitor and improve quality and safety can be embedded in routine activities of the team members, facilitated by HIT.[64,65]

Another component that contributes to patient-centeredness and care coordination is enhanced access. Enhanced access refers to the provision of clinical advice, as well as insurance information during and after office hours.[20,64] Some other innovations that encompass enhanced access include same-day scheduling, and email and telephone visits.[57] One health care system's efforts to improve patient-centered access involves a website that allows communication with physicians through secured e-mail, EMR and the provision of health promotion information.[66] Payment restructuring by: modifying the traditional fee-for-service with addition of new payment codes, instituting shared savings models that allow sharing of costs saved by decreased utilization, and incorporating fixed per member per month payments have all been used to enhance the sustainability of the PCMH model. However, there is yet a consensus on optimal payment models.[65,67,68]

The concept of PCMH is still in its developmental stage and early evaluations of the programs revealed generally positive but mixed outcomes particularly on quality measures.[65,69] More evidence by transparently testing the model in different environments is needed to determine whether PCMHs have a positive impact on patient-related outcomes. This evidence is needed before the concept will be fully embraced by various stakeholders.[69,70]

1.2.2.2 PCMH Standards According to National Committee for Quality Assurance (NCQA)

The Joint Principles publication (see section 1.2.2.1) was subsequently adopted by NCQA as Standards and Guidelines for Physician Practice Connections® - Patient-Centered Medical Home (PPPC-PCMH™) in 2008.[19,58] In 2014, NCQA updated the PCMH standards and guidelines to include the following six standards: Patient-Centered Access, Team-Based Care, Population Health Management, Care Management and Support, Care Coordination and Care Transitions, and Performance Measurement and Quality Improvement. A brief description of each standard is detailed in Table 1.1. To acquire three years of NCQA recognition, primary care facilities must achieve minimum scores as determined by the NCQA guidelines. Three recognition levels are available, depending on the points acquired by the facility, with level 3 being the highest.[19]

Table 1.1 Summary of NCQA PCMH 2014 Standards

Standard	Summary of Requirements
1. Patient-Centered Access	The practice provides 24/7 access to team-based care for both routine and urgent needs of patients/families/caregivers.
2. Team-based Care	The practice provides continuity of care using culturally and linguistically appropriate, team-based approaches.
3. Population Health Management	The practice provides evidence-based decision support and proactive care reminders based on complete patient information, health assessment and clinical data.
4. Care Management and Support	The practice systematically identifies individual patients and plans, manages and coordinates care, based on need.
5. Care Coordination and Care Transitions	The practice systematically tracks tests and coordinates care across specialty care, facility-based care and community organizations.
6. Performance Measurement and Quality Improvement	The practice uses performance data to identify opportunities for improvement and acts to improve clinical quality, efficiency and patient experience.

Source: Adapted from Standards and guidelines for NCQA's patient-centered medical home (PCMH), National Committee for Quality Assurance, 2014, page 14.

1.2.2.3 Implementation of PCMH

The Joint Principles and NCQA standards echo the increasing value of PCMH. The passing of the ACA reflects efforts to improve the quality and safety of health care and a priority to achieve this through PCMHs has also been emphasized.[4] Correspondingly, the potential of PCMHs in providing high quality care while reducing health care related costs has been embraced by several groups including ACOs. The PCMH model was also adopted by the Veterans Health Administration (VA) as the Patient Aligned Care Teams (PACTs) in 2010, and introduced by the Centers of Medicare and Medicaid Services (CMS) as PCMH demonstration programs with the goal to slow spending growth.[68,71] Likewise, community health centers and Federally Qualified Health Centers are being transformed into PCMHs.[19] As of May 2015, there are more than 10,000 practices recognized as PCMHs by NCQA.[72]

Despite that, the operationalization of the PCMH principles varies according to the interpretation of the institutions and implementation of PCMH differs from a narrow range that focuses on a specific clinical condition, to a broad approach to include PCMH in the institution across all conditions and patients.[28,73,74] Although the growing literature on PCMH generally reported positive outcomes, results are mixed.[28] Questions on the best definition, correlation between the degree of implementation and outcomes, and approach for transformation into PCMH still needs exploration.[75]

Regarding the PCMH transformation initiative, a qualitative analysis of the CMS National Demonstration Project aptly described practices transitioning into PCMH models.[76] Among the 36 practices with diverse geography, size, age, and ownership arrangements, transformation characteristics frequently described include: efficient use of EMR, effective communication, and role expansion of other medical staff such as medical assistants and nurse practitioners. In one large practice, authors also mentioned the inclusion of a clinical pharmacist on the health care team.

1.2.2.4 Outcomes of Integrated Care

Some publications, mainly studies from pilot and initial trials of PCMH implementation have reported encouraging outcomes on staff productivity, and health and utilization outcomes, therefore providing initial support for the viability of the model. The Veterans Health Administration (VA), the largest integrated US health system, with more than 5 million patients nationwide has demonstrated support for the PCMH structure. Two years after initiation in 2010, there were significant changes in utilization such as decrease in in-person primary care physician visits (53 to 43 per 100 patients per calendar quarter; $p<0.01$), increase in telephone care (2.7 to 28.8 per 100 patients per quarter; $p<0.01$), and improvement in post hospitalization follow-up (6.6% to 61% of VA hospital discharges).[77]

Other studies reported mixed findings of improved outcomes in various dimensions and limited improvement in other outcomes. For instance, the evaluation of patient outcomes 26 months after the National Demonstration Project of PCMH transformation found associations between the adoption of PCMH components with quality of care including improved access ($p=0.04$), better prevention ($p=0.001$) and quality of care scores ($p=0.007$). However, there were no improvements in chronic care scores and patient-rated outcomes (patient empowerment, general health status, satisfaction with the service relationship coordination of care, comprehensiveness of care, personal relationship over time, and global practice experience).[75]

Three other studies also reported mixed utilization outcomes. One study found associations between decreased ED visits and PCMH implementation while two other studies found no significant changes in ED visits. The first study include children with asthma and reported reduced rates of ED visits (incidence rate ratio = 0.93; 95% confidence interval = 0.89-0.97).[78] The second study, which was conducted in New York State, compared health care utilization outcomes in facilities with and without a PCMH structure. In this study, there were no significant differences for ED visits, primary care visits, radiology tests, laboratory tests, admissions, or readmissions. However, this study reported positive finding of fewer specialist visits in the intervention group one year after implementation of PCMH.[29] A third PCMH implementation study reported no significant changes in ED visits, inpatient admissions and quality measures.[30] Finally, a review that evaluated medical home outcomes published between 2007 and 2010, revealed decreased utilization of the ED and improvement in quality. This review however, reported the lack of evidence for enhanced patient or family experiences.[73]

One health care system (Group Health) with 20 primary care clinics in Washington State has been implementing PCMH reforms since 2002. These reforms include same-day appointment scheduling, direct access to specialists, primary care redesign, physician compensation, and an EMR with a patient web portal to enable

patient e-mail, online medication refills, and record review.[79] Despite the success in improving access, productivity and patient satisfaction, physicians' workload increased and resulted in decreased clinical quality.[80–82] Consequently, in 2006, the health care group implemented redesigns to address the problem at one PCMH prototype clinic in Seattle.[79,83] The health care system reported hiring more staff according to this ratio; for every 10,000 patients; 5.6 physicians, 5.6 medical assistants, 2.0 licensed practical nurses, 1.5 physician assistants or nurse practitioners, 1.2 registered nurses, and 1.0 clinical pharmacist. The follow-up comparison between the PCMH prototype clinic and control clinics showed reductions in ED visits and hospitalizations, and improvements in patients' experiences, quality and clinician burnout. Overall, after 2 years of PCMH prototype implementation, the estimated total savings was $10.30 per patient per month and the return on investment was $1.50 for every dollar spent to implement the PCMH.[83]

Conversely, one study which examined transitioning of small and solo primary care practices into PCMH models reported that although there are significant, modest improvements in some indicators of quality and efficiency, cost savings were not observed.[84] On the other hand, a recent study found that both higher levels and amount of change in PCMH implementation (based on NCQA scores) are related to higher quality of care and preventive services utilization, while higher levels of practice implementation were associated with lower overall medical and surgical costs.[28] More evidence on the effectiveness and sustainability of PCMH are therefore needed, especially regarding integration of pharmacists.

1.2.3 Roles of Clinical Pharmacists

The Institute of Medicine highlighted that optimal use of pharmaceuticals, the most common medical intervention, is a critical component in improving the national health care system.[1] However, drug related problems such as medication adherence and medication errors have long plagued modern medicine. Wilson et al. (2007) described the scenario of nonadherence to medication as a result of poor communication between

patient and prescriber. More than half of the elderly population in the US have more than one physician, but discussions with prescribers regarding the issues of multiple medications, or nonadherence due to side effects or costs are limited.[85] On a related note, conservative estimates showed that at least 1.5 million unnecessary adverse drug events in the US annually is a preventable problem that costs at least 200 billion dollars each year.[2] Transformation in the health care system is vital and involvement of various stakeholders, including patients, is needed to ensure success.[1]

The term "pharmaceutical care" emerged to the forefront by Hepler and Strand in 1990 and the American Society of Health-System Pharmacists vowed to focus on pharmaceutical care in 1993 as part of an effort to improve medication use and patient safety.[86,87] It is the "direct, responsible provision of medication-related care for the purpose of achieving definite outcomes that improve a patient's quality of life."[87] With that said, pharmacists, being the medication experts in optimizing therapeutic outcomes, are the most suitable health care practitioners to address the issues above.

According to the American College of Clinical Pharmacy (ACCP), besides embracing the philosophy of pharmaceutical care, clinical pharmacy involves in-depth understanding of medications, application of evidence-based therapy, and accountability for managing medication therapy to achieve therapeutic goals.[88] Throughout the years, training for clinical pharmacists has been enhanced and various pharmacist-provided services to optimize medication therapy in direct patient care settings have expanded.[88,89] In 2003, structured clinical pharmacy services, commonly referred to medication therapy management (MTM), became eligible for Medicare reimbursement and pharmacists were specifically named as a provider for these services.[89]

1.2.3.1 Medication Therapy Management (MTM)

MTM is a systematic process that assesses and evaluates patient's complete medication therapy regimen with focus on the patient, rather than the product.[18] The

comprehensive structure involves coordination with other practitioners to manage all other medications and medical conditions that the patient has and also empowers patients to actively manage their medications.[14,18] The provision of MTM varies according to the needs of the patients and settings but is typically conducted face-to-face for optimal interaction. Follow-up intervals also depend on the complexity of each patient; hence, personalization of the service.[18]

The five core elements according to the service model advocated by 8 pharmacy associations in the US are summarized below:

1. *Medication Therapy Review (MTR):* A systematic process of collecting patient-specific information, assessing medication therapies to identify medication-related problems, developing a prioritized list of medication-related problems, and creating a plan to resolve them.
2. *Personal Medication Record (PMR):* A comprehensive record of the patient's medications (prescription and nonprescription medications, herbal products, and other dietary supplements).
3. *Medication-Related Action Plan (MAP):* A patient-centric document containing a list of actions for the patient to use in tracking progress for self-management.
4. *Intervention and/or Referral:* The pharmacist provides consultative services and intervenes to address medication-related problems; when necessary, the pharmacist refers the patient to a physician or other health care professional.
5. *Documentation and Follow-up:* MTM services are documented in a consistent manner, and a follow-up MTM visit is scheduled based on the patient's medication-related needs, or the patient is transitioned from one care setting to another.

MTM has been implemented in a number of ways to manage the drug related problems according to the needs of the institution and improved outcomes have been reported. A retrospective study that examined outcomes among underserved diabetes

patients found higher adherence and lower HbA1c among patients who received pharmacist-directed MTM when compared with usual care.[90] A discharge MTM program in an extended care hospital had success in decreasing the number of discharge medications and readmission rates.[91] Interventions provided through telephone MTM program have also been reported to reduce medication-and health-related problems, and the associated costs.[92]

On the contrary, a recent meta-analysis found that there is insufficient evidence regarding the impact of MTM on health outcomes, although there is weak evidence on improvement in adherence and health care costs.[93] To maximize outcomes from clinical pharmacy services, it is important to prioritize services that have the most impact on patient health and is most need by the community. In other words, having a targeted approach on the disease state is recommended.[61,94] Typically, the positive effects of MTM are more significant for costly conditions such as diabetes, cardiovascular disease, asthma and cancer. MTM effectiveness also increases with disease severity, higher number of comorbidities and higher number of medications.[14,35] Consistent with this, a review of randomized controlled trials that evaluated the integration of MTM in a primary care medical home suggested that MTM is most efficient when patients with specific therapeutic problems are targeted, and when combined with effective communications and patient follow-up.[95]

The interventions provided by MTM are generally well received by providers and patients. Physicians appreciate the skills of pharmacists as part of the clinical team, and they have emphasized the importance of efficient communication and concise recommendations.[96] Regarding patients, they generally perceived personalized medication records and action plans, referral to other providers, and improved communication provided through MTM as important in improving their health condition.[96–98]

It is important to realize that MTM is an evolving field, with constant challenges and opportunities for researchers and policymakers. With the growing evidence of the relationship between MTM interventions and outcomes, the prospects of MTM expansion into integrated care is positive.[93]

1.2.3.2 Clinical Pharmacy Practice in Primary Care

Primary care typically provides the first contact between patient and providers. In comparison to specialist and tertiary care, patients in primary care are more likely to present themselves without an associated diagnosis and therefore, it is more common to have diagnostic uncertainty and encounter complex drug regimens in primary care.[61] For this reason, the World Medical Association (WMA) has identified primary care as the best access point to coordinate care for chronic conditions and to prevent medication errors.[99] Accordingly, the roles of clinical pharmacists, as key medication management providers, can have a significant impact on the delivery of primary care.[23]

Justified by the growing evidence that showed the value of pharmacists in team-based care models in acute care or outpatient settings, the notion of pharmacists working directly with primary care physicians has been developing and expanding.[23,61] The approval of specialty residency programs in ambulatory and community care pharmacy in 2009 by the Board of Pharmaceutical Specialties further strengthens the significance of clinical pharmacy practice in primary care.[100] Moreover, pharmacists have been recommended to be responsible for the continuity of pharmaceutical care when patients are transitioning from inpatient to outpatient care.[101]

The approach of clinical pharmacy services in primary care incorporates the concept of MTM, namely providing patient-centered medication therapy assessments, and may include other services such as ordering laboratory tests and medication adjustments.[23] For the latter purposes, written guidelines for authorizing and delegating the pharmacists' roles can be accomplished through collaborative drug therapy

management arrangements. The functions, procedures and decision-making criteria should be clearly defined.[24] Thus, collaborative practice agreements are important facilitators to optimize the roles of pharmacists. The agreements determine pharmacists' levels of autonomy in service provision, which may range from only monitoring medications and conditions to changing prescribed medications and prescribing medications.[35] More importantly, pharmacists' collaborative efforts to manage patients' therapy, such as medication therapy initiation and adjustment, may help reduce physician workload.[102]

In primary care settings, clinical pharmacists can provide individual or group consultations through direct or telephone interventions, and in various settings such as primary care offices, outpatient clinics, home visits, work-site health programs, senior centers, and community pharmacists' practices.[23] Apart from MTM services, pharmacists are often involved in preventive care such as immunizations, monitoring population registries together with the medical team, and administrative roles such as PCMH accreditation activities.[56] Besides collaboration with other health care providers, pharmacists also have sustained relationships with patients' families and caregivers.[23]

1.2.3.3 Pharmacist Involvement in PCMH

PCMH emphasizes provision of individualized medication assessment and tailored solutions.[14] Studies have shown that pharmacists are valuable resources for drug information and medication management when integrated into physician practice settings.[56] In a PCMH establishment, the pharmacist's roles include[24]: 1) Identifying, resolving, preventing, and monitoring medication use and safety problems; 2) Reducing polypharmacy and optimizing medication regimens on the basis of evidence-based guidelines; 3) Recommending cost-effective therapies; 4) Designing tailored adherence and health literacy programs; 5) Developing patient medication action plans with self-management goals; 6) Communicating medication care plans to patients, providers, and other entities in the patient's health care delivery system.

However, pharmacists are often underused despite their training and expertise in medication management.[23,103] Recent initiatives that recognized the value of pharmacists include the Patient Safety and Clinical Pharmacy Services Collaborative (2008) and Patient-Centered Primary Care Collaborative (2012), that emphasized the importance of pharmacist integration and comprehensive medication management service.[14,103]

As pharmacy services expand, successful examples of pharmacists' contributions, outcomes resulting from the integration of pharmacists into primary care practices and lessons learned can inform and motivate other pharmacists to participate in PCMH.[4] A study based in Michigan described the integration of pharmacists into PCMH structure at eight general medicine practices.[35] Pharmacists were positioned to substitute various aspects or augment physician care, help achieve quality indicators and increase revenue through billing of clinical pharmacy services. The inclusion of pharmacists in the PCMH model provided an opportunity to standardize ambulatory pharmacy care across different sites, which were operating in a 'silo' prior to PCMH implementation. Further, PCMH pharmacists were added into five other health centers that did not have pharmacists. In their model of care, pharmacists were responsible for evaluating and optimizing therapeutic regimens to achieve treatment goals for diabetes, hypertension, hyperlipidemia, and polypharmacy. Patients were identified through proactive screening of patient registries, or physician referral. Pharmacists discussed the patients' conditions with their physicians and managed the diseases according to clinical practice guidelines. In this study, the mean number of patients ranged from 2.2 to 6 patients per half-day clinics (range from 1 to 6).

It is noteworthy to highlight another pharmacist-integrated PCMH in North Carolina (Mountain Area Health Education Family Health Center) that has been recognized as a level 3 PCMH by NCQA.[104] The Department of Pharmacotherapy is embedded in the family medicine clinic and pharmacists provide MTM, anticoagulation,

and osteoporosis clinical services. The structure of the PCMH is led by primary care physicians and supported by team members which include pharmacists, nurses, behavioral medicine providers, physician assistants, nutritionists, Spanish interpreters, and case managers. Medication reviews are typically conducted for complex medication regimens, diabetes management and medication assistance. By having accountability for patients as part of the team, pharmacists contribute to the joint principles of PCMH. Descriptions of how pharmacist activities fulfill the Joint Principles of PCMH[21] are illustrated in Table 1.2.

Table 1.2 Examples of pharmacist activities based on the Joint Principles of PCMH

Joint principle[1]	Description[1]	Examples of pharmacist activities
Principle 1: Personal physician	Each patient has an ongoing relationship with a personal physician trained to provide first-contact, continuous, and comprehensive care.	Each patient has a personal physician.
Principle 2: Physician-directed medical practice	The personal physician leads a team of individuals at the practice level that is collectively responsible for the ongoing care of patients.	Team members embedded in the practice include pharmacists, nutritionists, physician extenders, case managers, translators, behavioral medicine providers, billing staff, nurses, laboratory staff, information technology staff, and administrative support staff.
Principle 3: Whole-person orientation	The personal physician is responsible for meeting all health care needs of the patient or taking responsibility for appropriately arranging care with other qualified professionals. This includes care for all stages of life: acute care, chronic care, preventive services, and end-of-life care.	Pharmacists are considered "other qualified professionals"; provide care in hospitals, clinics, and continuing care facilities; focus on provision of MTM services; and serve as consultants, immunizers, educators, and clinical pharmacist practitioners.
Principle 4: Coordinated and integrated care	Care coordination and integration is provided across all elements of the complex health care system. Care is facilitated by registries, health information exchange, and other means to ensure that patients receive the indicated care, in a culturally and linguistically appropriate manner.	Pharmacists ensure access to community resources, assist with transitions in care, communicate with team members via an electronic medical record, and use translators for non–English-speaking patients.
Principle 5: Quality and safety	(1) Practice advocates for their patients; (2) evidence-based medicine and clinical decision-making tools guide decisions; (3) physicians accept accountability for quality improvement; (4) patients participate in decision making; (5) information technology supports patient care, performance measurement, patient education, and enhanced communication; (6) patients undergo voluntary process for PCMH recognition; and (7) patients and families participate in quality improvement.	Pharmacists apply and teach evidence-based medicine, practice a patient-centered philosophy, lead quality improvement initiatives including interprofessional teams that seek to improve quality of care, collaborate with information technology to develop and use pharmacotherapy-specific templates, and assist with NCQA application.
Principle 6: Enhanced access	Care is available through systems such as open scheduling, expanded hours, and new options for communication among patients, personal physician, and practice staff.	Pharmacists serve as extenders for MTM , increasing patient access to chronic care services.
Principle 7: Payment recognizes value of PCMH	Payers recognize the added value provided to patients who have a PCMH.	Pharmacists bill for cognitive services; contributions to quality improvement efforts increase reimbursement potential through pay-for-performance and care management pilot projects.

Abbreviation used: MTM, medication therapy management; NCQA, National Committee for Quality Assurance; PCMH, patient-centered medical home.

Source: Adapted from "Integration of pharmacists into a patient-centered medical home", by M.A. Scott, B. Hitch, L. Ray and G. Colvin, 2011, *Journal of the American Pharmacists Association*, page 163.

1.2.4 Integration of Pharmacists in Team-based Care

The importance of team-based expertise in providing quality health care cannot be underestimated.[17] The literature shows that team care with pharmacist-provided direct patient care yields positive therapeutic and safety outcomes.[105] Therefore, pharmacists are well suited health care practitioners to work in interdisciplinary primary care teams, providing their expertise in comprehensive medication management, particularly for patients with chronic conditions.[14,23]

Different approaches have been applied to integrate pharmacists into collaborative care. Clinical pharmacy services can be set up in various settings such as physician offices, hospital-based outpatient clinics, and pharmacies.[106] Pharmacists can also be engaged on a full-time or part-time basis, providing services directly in the medical practice facility or in community pharmacies through contracts and collaborative agreements.[56] When possible, the setting to provide pharmacy services should be near the referring physicians as the proximity promotes collaboration, enhances communication and encourages referrals.[106]

1.2.4.1 Integration of Pharmacists in PCMH

The development of a PCMH is unique to the needs of the institution, and thus the integration of pharmacists into the structure should be tailored accordingly for success.[94,106] Pharmacists can be employed as full-time staff to conduct consultations in the PCMH practice itself, or contracted as a part-time pharmacist to provide services around the community, which allows for more flexibility.[24,107] An advantage of having in-house pharmacists in the medical home is that primary care providers can omit referral to medical specialists for medication adjustments as pharmacists can perform medication management more cost effectively.[23]

Pharmacist can provide services externally through embedded, regional, contracted and external models. In the embedded model, pharmacists can practice in the

PCMH through partnership with hospital pharmacy or pharmacy schools that may involve training of Pharm.D. students and pharmacy residents. In the regional model, the contracted pharmacist typically works in a health system or health plan that serves several PCMHs in the region. Contracted and external models are suitable for smaller physician practices as pharmacists are not typically employed full-time and there is more flexibility for patients in terms of when and where services are provided.[24] The external model also allows for the participation of community pharmacists in PCMH.[24]

In terms of clinical pharmacy services integration, the pharmacist may meet patients prior to, during or after the primary care appointment.[24] For instance, pharmacists may see patients via a pre-visit approach in collaboration with the medical home team and later share the care plan recommendations with the physician before or after a physician visit.[23] Patients who did not reach therapeutic goals, were on high risk medications, with complex drug regimens, or have multiple prescribers for MTM services, can be identified by pharmacists, or referred by providers for a separate follow-up pharmacist visit.[24]

There are many ways for physicians to refer patients to pharmacists. Generally, targeted referrals through physician self-initiated referral or predetermined criteria from databases are more efficient in selecting patients in need of the services.[24,61] Findings from a Canadian project suggest that targeted physician referral of patients with specific needs is more effective than referral of patients with at least 5 medications.[61] Referrals can also come from any team member for issues relating to drug therapy.[104] Again, the best referral method depends on the needs of the institution and the pharmacist should plan for the best strategies together with the PCMH team.[61]

Regardless of the integration methods, details of job descriptions, referrals, documentation, time and place of service should be clearly defined.[94] The importance of these elements has been highlighted by a case study in Chicago. The pilot PCMH

included a pharmacist in an administrative position for the PCMH operations and analytics committee. This helped with the development of the pharmacist's role and it also built physicians' trust. The approach was described as very successful, to the extent that referrals to the pharmacist were subsequently higher than what could be met. Collaborative practice agreements were also in place, allowing pharmacists to initiate, discontinue or titrate medications based on patient results and tolerance.[108]

1.2.4.2 Impact and Outcomes of Clinical Pharmacists in Integrated Care

Pharmacist services are usually provided for chronic diseases like hypertension, diabetes and asthma. There are also clinical pharmacy services provided for conditions such as osteoporosis, epilepsy and infection, although this is less common. Clinical, utilization and costs outcomes that compared pharmacist-integrated models with that of usual care reported mixed results that lean towards outcomes improvements with pharmacy services.

One randomized control trial published in 2008 (n=463) compared physician-pharmacist collaboration and usual care for the control of hypertension. Subjects receiving the intervention achieved significantly lower primary outcomes of systolic (p= 0.007) and diastolic (p=0.002) blood pressures compared to the control group (137/75 mmHg vs. 143/78 mmHg, respectively). Secondary measures at 12-month follow-up showed significantly higher blood pressure goal attainment of <140/90 mmHg, higher total office visits, fewer physician visits, and more prescriptions for antihypertensive medications for patients who received collaborative care. There were minimal differences between the groups in hypertension-related knowledge, medication adherence, quality of life, and satisfaction.[109]

An MTM program focused on hypertension and dyslipidemia in Asheville reported positive clinical (n=565) and economic (n=620) outcomes. The pharmacists provided cardiovascular or cerebrovascular risk reduction education, long-term follow-

up, monitoring and recommendations to physicians. These interventions significantly improved cardiovascular health indicators over the course of the study: mean systolic blood pressure (137.3±16.85 to 126.3±14.20 mmHg); mean diastolic blood pressure (82.6±11.62 to 77.8±9.67 mmHg); percentage of patients at blood pressure goal (40.2% to 67.4%); mean low-density lipoprotein (LDL) cholesterol (127.2±36.60 to 108.3±32.06 mg/dL); percentage of patients at LDL cholesterol goal (49.9% to 74.6%); mean total cholesterol (211.4±45.70 to 184.3±38.55 mg/dL); and mean serum triglycerides (192.8±171.41 to 154.4±88.35 mg/dL). There were no differences in mean high-density lipoprotein (HDL) cholesterol (48±13.35 to 46.6±12.24 mg/dL). However, over the 6-year study period, the cardiovascular or cerebrovascular event rate declined to almost half of the baseline rate (77 per 1,000 person–years to 38 per 1,000 person–years).[110]

Regarding economic outcomes, mean cost per cardiovascular or cerebrovascular event in the study period was $9,931, compared with $14,343 during the historical period. Although medication use increased nearly threefold, related medical costs decreased by 46.5%. Cardiovascular or cerebrovascular related medical costs also decreased from 30.6% of total health care costs to 19%. The results of this study demonstrated sustainable outcomes from pharmacist interventions for as long as 6 years.[110]

Clinical pharmacy services integrated into another PCMH structure with an osteoporosis clinic contributed to the increase of appropriate calcium and vitamin D use from 30% at baseline to 99% at follow up.[104] Another interesting pilot study involving pharmacist intervention, which combined traditional MTM and lifestyle medicine intervention for patients with chronic conditions reported improvements in total cholesterol, low-density lipoprotein cholesterol, blood glucose, body weight, physical activity level, fruit and vegetable intake, risk for myocardial infarction, risk for any cardiovascular disease event, self-reported unhealthy days, and qualitative survey data.[111] Other published studies demonstrate that inclusion of a pharmacist in the medical team of

a tertiary hospital significantly shorten length of stays, and lower both pharmacy and total hospital costs, while addition of a pharmacist to a pulmonologist practice improve asthma self-management.[112,113]

Inclusion of pharmacists in primary care practices has also helped to achieve PCMH accreditation by increasing chronic care quality measures, as discussed in a recent publication.[114] This was achieved through pharmacists' recommendations on the use of angiotensin-converting enzyme inhibitor (ACEI) or angiotensin II receptor blocker (ARB) medications to patients with concomitant diabetes mellitus and hypertension. Another outcome of this study is the positive recommendations acceptance rate. Physicians agreed with recommendations to initiate therapy in 54.7% of the patients, and therapy was started in 68.3% of those patients.[114] The acceptance rate for pharmacists' recommendations is even higher in a randomized control study conducted in 24 sites in Ontario. Specifically, physicians implemented or attempted to implement 72.3% of the recommendations. These results reflect that physicians are receptive to recommendations to resolve drug-related problems. In the latter study however, pharmacists' interventions did not yield any significant changes in health care use or cost outcomes.[115]

Finally, Chisholm-Burns (2010) and colleagues examined 298 studies in a systematic review and meta-analyses that examined the effects of pharmacists as team members on patient care. The meta-analyses found that HbA1c, LDL cholesterol, blood pressure, adverse drug events, medication adherence, patient knowledge, and quality of life, were all favorable towards pharmacists' direct patient care over comparative services ($p<0.05$).

Consistent with the PCMH principles to provide continuous patient-centered care, pharmacists are typically integrated in care teams for chronic diseases to enhance the quality and safety of health care. Impact of these efforts have been examined from a broad range of outcomes, from clinical, utilization and economic outcomes, as well as

physician acceptance rate for pharmacists interventions. Although some studies did not find significant changes in outcomes, the Asheville study demonstrated not only positive improvements for the patients, but that these outcomes are sustained over the long-term. These evidence, together with the comprehensive review by Chisholm-Burns, serve as strong support for the inclusion of pharmacists as key members of the health care team. Although this support exists in the literature, several challenges and barriers may impede pharmacists being fully integrated into primary care settings. Below is a discussion of several challenges and barriers regarding pharmacist involvement in collaborative care.

1.2.4.3 Challenges and Barriers for Pharmacists in Collaborative Care

Despite the changing landscape of primary care, many physicians may not have worked with pharmacists in such a direct manner and this can therefore lead to unique challenges.[4,116] Foreseeing challenges and being preemptive in tackling the barriers in the integration of pharmacists in PCMH is vital to promote effective collaboration and to provide the best care to patients.

First, due to the physician-led structure of PCMH, it may be easy to forget the inclusion of other health care practitioners including pharmacists.[4] Many clinicians are also not familiar with pharmacists' training and skills.[23] Besides the need to educate physicians regarding the scope of clinical pharmacists' responsibilities, there is also a need to cross-train and foster understanding among other team members to promote transparency and to improve transfer of information in integrated care. Acknowledgement of the pharmacists' roles in PCMH should be supported at all levels and pharmacists must be proactive in demonstrating their value and interest to be part of the PCMH team.[4]

Next, payment has been repeatedly discussed as a major barrier to the integration of pharmacists in MTM and collaborative care. To date, there is no consensus on a systematic payment model that adequately compensates clinical pharmacist services.[4,23]

Hence, calls for more outcomes studies related to pharmacist services should be encouraged with the aim to develop payment models for the services.[4] One recommendation is to pay according to performance bonuses and care coordination.[23] For small practices (one or two physicians), contracting clinical pharmacists for targeted patients is recommended as the inclusion of pharmacists in such a scenario may not be cost-effective.[23] Besides payment issues, communication is of vital importance.

Heather and colleagues (2015) have identified issues within the arena of pharmacist-physician communication. These include weakness of electronic communications and the absence of pharmacists onsite, all of which may lead to misunderstanding and defensiveness regarding recommendations.[116] Surprisingly, although utilization of medical information technology and EMR is increasing, efforts to ensure that the system is working effectively for integrated care are still needed.[4] Additionally, it has been reported that community-based pharmacists typically do not have access to complete patient charts and have to depend on calling or faxing to gather relevant information, which interrupts conducive work flow and risks misinterpretation of information.[23] Nevertheless, the EMR has been reported to successfully facilitate coordination in PCMH. This is demonstrated in a decentralized PCMH setting with 16 offices and one pharmacist. In this PCMH, the pharmacist effectively reviews patient charts from a central office location through the EMR.[114]

Overall, for a successful integration into the PCMH model, pharmacists should communicate regularly within and outside the pharmacy profession including state associations; advocate for efficient information technology and payment structures; be resourceful; and perform collaborative pharmacist services to generate trust for sustainable relationships. Standards and accreditations may provide guidelines, but the full potential of pharmacists cannot be achieved without addressing the issues and barriers pertaining to the roles of pharmacists in PCMHs.[4] Rigorous assessments that detail the involvement of pharmacists in the team, decision making, care quality, and

clinical endpoints should be conducted to determine best practices for integration.[23] Despite the challenges, pharmacists are gradually gaining recognition for their expertise and competence, and eventually getting more acclimated to collaboration.[117]

1.2.5 Federally Qualified Health Centers (FQHCs)

With current advancements in the medical field, there is still disenfranchisement of access to primary care and a shortage of primary care providers, especially in low-income areas, and among rural residents, ethnic minorities, and the uninsured.[118] Evidence has shown that access to primary care can help mitigate disparities in the health care system.[119] Community Health Centers (CHCs) have provided high quality primary care to the underserved and have saved over $20 billion annually in health care system expenditures.[118] CHCs typically serve low-income ethnic minorities, who are uninsured or are publicly-insured. Therefore, these centers serve as the bridge to provide primary care to this vulnerable population. CHCs that operate under specific federal standards are designated as federally qualified health centers (FQHCs).[57,118,120]

FQHCs are "safety net" outpatient clinics enacted under Medicare in 1991 to provide primary care services in underserved urban and rural communities.[121] They are mandated to serve all patients without regard to their ability to pay and a sliding fee scale is available for the uninsured.[57,118,122] In addition to CHCs, public housing centers, outpatient health programs funded by the Indian Health Service, and programs serving migrants and the homeless are other examples of FQHCs facilities.[121] FQHCs qualify for specific reimbursement systems under Medicare and Medicaid and funds are dispersed from the Health Resources and Services Administration (HRSA) through the Bureau of Primary Health Care.[119,120,123] Federal government owned or sponsored primary care facilities such as CHCs are part of the government's actions to address access to primary care.[57] FQHCs are usually governed by a board of directors comprised of people who use the health center.[122] Services provided include physician, nurse and dental services, as well as medications, diabetes self-management training, social services, mental health

services, preventive health screenings and women's health services.[121,123]

CHCs, specifically FQHCs are traditionally focused on cultural competence, team work and patient-centrism.[119] Furthermore, a systematic review supported the value of multidisciplinary teams and community outreach in addressing disparities in chronic diseases.[124] Therefore, FQHCs are in an optimal position to be developed as PCMHs and to focus on reducing health care disparities by providing access to quality primary interprofessional care.[119,122] Advanced FQHCs with a PCMH model have also been associated with improved provision of preventative services and health outcomes.[122] Below is a description of FQHCs in central Texas, which serve as the site for this study.

1.2.5.1 CommUnityCare in Travis County, Texas

Health clinics were established in Travis County in 1970 to provide primary care, dental care and family planning for low-income individuals and the uninsured. In 2001, the CHCs received a federal grant which led to their qualification as FQHCs.[125] In 2009, the network became a private, non-profit corporation under the name of CommUnityCare, with the majority of funding from Central Health (Travis County's public entity that focuses on access to underserved communities) and the Federal Bureau of Primary Health Care, with additional funding from public and private grants.[125,126]

As of 2014, CommUnityCare clinics are available at 23 locations in Travis County, serving more than 80,000 patients.[127] Primary care, dental care, behavioral health and specialty services are provided to Travis County residents with low-income and no private insurance.[128] CommUnityCare has incorporated the concept of PCMH in several of their health centers with team-based care that adheres to evidence-based medicine, patient and family empowerment, and participation.[129] Travis County FQHC PCMHs involved pharmacists in their model of collaborative care for patients with chronic diseases, including diabetes. The next section provides a brief overview of the disease state of interest in this study: diabetes.

1.2.6 Diabetes Mellitus

Diabetes mellitus is a chronic metabolic disease due to defects in the pancreas resulting in insufficient insulin production (insulin deficiency), or inability of the cells to respond to insulin (insulin resistance), or both.[130–132] Consequently, glucose in the blood fails to be absorbed into the cells, leading to hyperglycemia. Symptoms of diabetes mellitus include frequent urination (polyuria), lethargy, weight loss, excessive thirst (polydipsia), and hunger (polyphagia).[130,132] Chronic hyperglycemia is associated with long-term complications such as microvascular complications (retinopathy with potential loss of vision; nephropathy leading to renal failure; peripheral neuropathy with risk of foot ulcers and amputations) and macrovascular complications (coronary artery disease, stroke, peripheral arterial disease).[130] Besides that, diabetes patients have increased the risk of hypertension and dyslipidemia.[7,130]

The etiology of diabetes remains unclear although it has been related to both genetic and environmental factors.[131,132] The two main types of diabetes are Type I and Type II diabetes. Approximately 5-10% of diabetes patients are diagnosed with Type I or insulin-dependent diabetes, where the pancreas produces little or no insulin. The most common form of diabetes that affects 90-95% of diabetes patients is Type II or noninsulin-dependent diabetes, where the pancreas produces sufficient insulin but it is not efficiently utilized by the tissues. Type I diabetes is typically diagnosed in children or young adults while Type II diabetes is most commonly diagnosed in adults.[130–132] Obesity, race, metabolic syndrome (hypertension and hyperlipidemia), age and family history have been associated with higher risks of developing Type II diabetes. Other less common types of diabetes include gestational diabetes, genetic defects of beta-cell function or insulin action, disease of the exocrine pancreas, and drug- or chemical-induced diabetes.[130]

1.2.6.1 Prevalence, Incidence, Morbidity, Mortality and Burden of Diabetes Mellitus

According to the World Health Organization (WHO), the global prevalence of diabetes in 2014 was estimated to be 9% and diabetes was responsible for an estimated 1.5 million deaths in 2012.[5] The burden of the disease is predicted to increase in developing and developed countries worldwide.[133] According to the data from Centers for Disease Control and Prevention (CDC), diabetes is becoming more prevalent in the US and number of Americans with diagnosed diabetes increased more than threefold from 1980 to 2014.[6] In 2014, the United States alone was estimated to have 29.1 million people with diabetes, which is equivalent to 9.3% of the U.S. population. Of this, approximately one-third is undiagnosed. Prevalence of diabetes is found to be the highest among those 65 years and older (11.2 million, 25.9%) and in men (15.5 million, 13.6%). Statistics from 2010 to 2012 report that American Indians have the highest percentage of diagnosed diabetes, followed by non-Hispanic blacks and Hispanics. For those under 20 years of age, about 200,000 people have diagnosed diabetes, corresponding to about 0.25% of the population in this age group.[7]

Data from 2012 shows that there are 1.7 million new cases of new diabetes diagnoses among adults over 20 years of age, translating to 7.8 cases per 1000 people. Additionally, it is estimated that there are 86 million Americans with prediabetes.[7] Boyle and colleagues (2010) have projected the prevalence of diabetes in the US to increase to 25 – 28%, and the incidence of diabetes to increase to 15 cases per 1000 people by 2050.[134]

Because diabetes can affect many parts of the body, long-term complications from diabetes are major causes of morbidity and death.[7,131] According to the most recent data from the CDC, hypoglycemia and hyperglycemic crises contributed to more than 450,000 emergency room visits. Of all adult diabetes patients over 18 years old, 71% have high blood pressure and 65% have high LDL cholesterol. Hospitalization rates for heart attack and stroke are 1.8 and 1.5 times higher, respectively, among adults with diagnosed

diabetes as compared to those without. Microvascular complications are responsible for retinopathy in more than 30% of the diabetes population. These complications are also a primary cause in 44% of new cases of kidney failure, and 60% of non-traumatic lower-limb amputations in people with diagnosed diabetes. Additionally, diabetes can also lead to nerve disease, non-alcoholic fatty liver disease, periodontal (gum) disease, hearing loss, erectile dysfunction, depression, and complications during pregnancy.[7]

In terms of mortality, diabetes has been reported as the seventh leading cause of death in the US in 2010. Diabetes has been listed as the underlying cause of death and mentioned as a cause of death in 69,071 and 234,051 death certificates, respectively. The actual number may be higher as these figures may be underreported. In addition, earlier data estimated that rates of death from all causes were about 1.5 times higher among adults aged 18 years or older with diagnosed diabetes than among adults without diagnosed diabetes.[7]

For the year 2012, the total cost of diabetes in the U.S. was estimated at $245 billion. This is further divided into $176 billion in direct medical costs and $69 billion in reduced productivity. Hospital inpatient care accounts for the higher proportion in the total medical cost (43%), followed by prescription medications to treat the complications of diabetes (18%), antidiabetic agents and diabetes supplies (12%), physician visits (9%), and nursing/residential facility stays (8%). Along with this, the average medical expenditures for people with diagnosed diabetes was 2.3 times higher than those without diabetes.[135]

This data, together, excluding costs of intangible pain and suffering, and those from undiagnosed diabetes, clearly underscores the disproportionate burden that diabetes imposes on society.[135] Diabetes is a classic example of a disease that needs patient-centered care, which may be achievable through a PCMH model.

1.2.6.2 Management of Diabetes Mellitus

Diabetes is diagnosed based on the laboratory criteria of the amount of glucose in the blood, specifically when any one of the conditions below is met (Table 1.3):

Table 1.3 Criteria for the diagnosis of diabetes

Test criteria	**Threshold level**	**Note**
HbA1c	≥ 6.5%	
Fasting plasma glucose (FPG)	≥ 126 mg/dL (7.0mmol/L)	Fasting is defined as no caloric intake for at least 8 hours
Two-hour plasma glucose (2-h PG) during oral glucose tolerance test (OGTT)	≥ 200mg/dL (11.1mmol/L)	OGTT test should be performed using a glucose load containing the equivalent of 75g anhydrous glucose dissolved in water
Random plasma glucose	≥ 200mg/dL (11.1mmol/L)	In patients with classic symptoms of hyperglycemia or hyperglycemic crisis

Source: Adapted from "Standards of medical care in diabetes 2014", American Diabetes Association, *Diabetes Care,* 2014, page S15.

Glycated hemoglobin A1c or commonly abbreviated as HbA1c is the objective measure for glycemic control and is the gold standard for monitoring diabetes over time. HbA1c reflects average plasma glucose levels over the previous 8 to 12 weeks. Management guidelines recommend HbA1c measurement every 3 months to determine if target control is met, especially for patients who do not meet therapy goals or had recent therapy changes.[136,137] For patients who have stable glycemic control or who are meeting treatment goals, it is that they receive two HbA1c tests a year. Alternatively, testing with point of care (POC) devices allows for more convenience and more timely treatment adjustments.[137]

The general target level of HbA1c in the US is less than 7%, although the target should be individualized according to the treatment regimen, complications risk, comorbidities, life expectancy and patient preferences.[137,138] For example, diabetes patients with microalbuminuria (an indication of poor renal function) will have a lower

target range for the purpose of lowering the cardiovascular risk. In contrast, the target range for the elderly and patients with shorter life expectancy may be higher. [138]

Irrespective of the HbA1c target, evidence from the US[139] and UK[140] populations have showed that any reduction in HbA1c is significantly associated with reductions in risk of complications. The UK prospective diabetes study (UKDPS) specified that a 1% reduction in HbA1c is associated with reductions in the following: 21% reductions in risk for any end point related to diabetes (95% confidence interval 17% to 24%, $p < 0.0001$), 21% for deaths related to diabetes (15% to 27%, $p<0.0001$), 14% for myocardial infarction (8% to 21%, $p<0.0001$), and 37% for microvascular complications (33% to 41%, $p<0.0001$).[140]

To achieve HbA1c reduction, diet changes, weight control and physical activities are necessary.[132,137,141] Pharmacological invention is usually started for more severe patients upon diagnosis, or it may be added when lifestyle interventions fail to control the diabetes.[141] Diabetes medications may include single or multiple oral medications (e.g., metformin, sulphonylureas, glitazones and acarbose) or insulin injections, or a combination of both.[132,137,138,141] Insulin is usually the main agent for Type I diabetes patients, and commonly indicated for many patients with Type II diabetes due to the progressive nature of Type II diabetes.[137]

Medications cannot be successful in managing glucose levels of the patient without management of caloric intake and weight. Details on carbohydrate counting, alcohol consumption, sodium intake, targets for weight loss should be provided to patients to assist in the control of this noncommunicable disease.[137] These can be achieved through diabetes education, which is critical for diabetes management. Structured education programs during the diagnosis stage and subsequently, on a regular basis that is facilitated by group education on self-care directed by skilled professionals is highly recommended.[138]

Throughout the years, diabetes care has shifted from hospitals to primary care and it is usually first diagnosed and managed by primary care physicians.[142,143] For that reason, diabetologic education and self-care as tools that empower diabetes patients with the knowledge and support to manage their condition should be provided in primary, outpatient and community care settings, with the ultimate objective to prevent or slow the development of complications.[137,143] Diabetes education should foster patient participation based on patient-centeredness, an approach that is also emphasized in PCMH. To elaborate, diabetes education and support may include dietetic information, pharmacological treatment, physical exercise, complications, self-care of feet, psychosocial issue management and self-analysis for insulin dose adjustment.[137,138] Numerous studies have reported that these structures help to improve clinical outcomes, quality of life and overall costs.[137]

Because the care for diabetes patients is multifaceted, a team-based approach that may include physicians, nurse practitioners, physician's assistants, dietitians, pharmacists, and mental health professionals with expertise in diabetes is important.[137,138] Pharmacists, are an important asset to enhance medication adherence, and to provide related diabetes education. Diabetes related outcomes from team-based care with pharmacist integration are discussed in the following section.

1.2.6.3 Diabetes Outcomes with Pharmacist in Integrated Care

The Asheville project in North Carolina is the landmark study that provided evidence for the contributions of pharmacists in the management of diabetes. Pharmacists based in community pharmacies were certified diabetes educators who provided long-term follow-up, clinical assessment, goal setting, monitoring, and collaborative drug therapy management with physicians. The pharmaceutical care services conducted throughout the 5-year study resulted in a reduction of mean HbA1c and lipid levels at all follow-ups, with more than 50% of patients demonstrating improvement at each

measurement. The number of patients with optimal A1c values (<7%) also increased at each follow-up. Besides that, adherence to self-care (e.g., foot exams and self-monitoring of blood glucose) improved. Regarding economic outcomes, costs shifted from inpatient and outpatient physician services to prescriptions, which increased significantly at every follow-up. Total mean direct medical costs decreased by $1,200 to $1,872 per patient per year compared with the baseline. Days of sick time decreased every year (1997–2001) for one employer group, with estimated increases in productivity estimated at $18,000 annually.[144]

Numerous studies have reported similar outcomes since the Asheville project, particularly with clinical outcomes (e.g., HbA1c, LDL and blood pressure).[33,105,145,146] For example, a pharmacist-led clinic in Pittsburg, Pennsylvania improved outcomes in HbA1c, body mass index (BMI), LDL, HDL, total cholesterol, triglycerides and blood pressure.[107] In another study in a VA setting, pharmacist-led group appointments targeted for diabetes patients with depression revealed a greater change in the proportion of participants achieving HbA1c <7% in the treatment arm than with standard care (29.6% vs 11.9%), with odds ratio 3.6 (95% CI 1.1 to 12.3).[147]

A 2014 review of collaborative pharmacy practice demonstrated that in addition to improvement in clinical measures, pharmacists practicing in a variety of outpatient environments can also improve adherence to standards recommended by the American Diabetes Association (ADA). The ADA guidelines include yearly monofilament exams, dilated eye exams, microalbumin screening and flu/pneumococcal vaccines.[146] Likewise, one study with the specific intervention of pharmacist-provided diabetes assessment services one week prior to physician appointment (n=314) in a university-based family medical center found significantly higher proportion of each standard completed (glycosylated hemoglobin, lipids, foot exam, eye referral, pneumococcal and influenza vaccination, and urine microalbumin) when compared with the control group ($p < 0.001$).[148]

Conversely, another VA health care system that integrated pharmacists in 196 primary care clinics found no significant association between pharmacist presence and oral hypoglycemic agent adherence. The authors suggested reexamining the exact roles of pharmacists and a better understanding of their roles to maximize this resource to improve patient outcomes.[149]

Published PCMH studies have also shown positive health care utilization outcomes on chronic diseases. Implementation of PCMH was associated with savings in ED utilization (23% less than projected), outpatient care (25% less than projected), and pharmacy (11% less than projected) in a community setting.[150] One other innovative collaborative study with pharmacists integrated into the team, reported a reduction in all-cause admissions, readmissions and cost savings for health plan members with diabetes.[151] A previous study conducted to evaluate the changes in diabetes-related hospitalization and ED visits for patients in CommUnityCare found a significant increase of eight hospitalizations (8 visits per 220 patients, mean = 0.036, SD = 0.284) for patients in the control group while the intervention group had a decrease of one hospitalization (-1 visit per 220 patients, mean = - 0.005, SD = 0.278). Although the change in ED visits was not significant in this study, patients in the control group had a higher increase of 16 ED visits (16 visits per 220 patients, mean = 0.073, SD = 0.584), as compared to the intervention group which had an increase of 4 ED visits (4 visits per 220 patients, mean = 0.018, SD = 0.641).[152] Overall, the literature that compared the impact of PCMH pharmacists in diabetes focused on clinical outcomes, and there is a dearth of publications that document utilization outcomes.

1.2.6.4 Cost Effectiveness of Integrated Models

Apart from improving clinical outcomes, lowering of health care costs is also an important aim of PCMHs.[27] Similar to other outcomes, the impact of pharmacists on economic outcomes is also equivocal. According to the latest report by Patient-Centered

Primary Care Collaborative (PCPCC), more than half of the studies (17 out of 28 studies) published between September 2013 and November 2014 indicate improvement in costs with primary care PCMH interventions.[153]

Four published studies highlighted improved outcomes and cost savings while another two studies found no overall change in total costs. The first study, which was based in Ohio, compared the direct participation of a pharmacist on a patient care team with a control team. Hospital stays, pharmacy and total hospital costs were all lower at the end of this 9-month study.[112] Similarly, another study found that MTM interventions lowered the odds of hospitalization and hospitalization costs for patients with diabetes or heart failure. However, there was no improvement in patient satisfaction and health-related quality of life.[93] Lower median per member per month health care costs have been observed in an MTM system developed over 13 years in an integrated health system in Minnesota, when compared to usual care sites.[154] One study attempted to assess health and cost outcomes over a 20-year period. The simulated controlled trial data suggests that PCMH can cost-effectively reduce complications and mortality from diabetes ($7898 per quality-adjusted life year).[155]

Two PCMH studies found no overall savings in costs. Group Health's pilot PCMH clinics in Seattle reported that primary care costs were significantly higher and ED visits were also significantly lower, which resulted in no significant differences in overall costs after 12 months of PCMH implementation.[79] In contrast, another publication that examined Group Health's outcomes in diabetes patients reported increases in ED visits.[156] In a separate multi-payer medical home pilot implementation, neither hospital, ED, or ambulatory care services nor total utilization costs were reduced over 3 years.[157]

Ackroyd and Wexler (2014) have discussed that evaluating costs in diabetes is challenging as savings may only be observed over a long term (e.g. multiple years). It should also be noted that the discussion on cost-effectiveness is not meaningful without

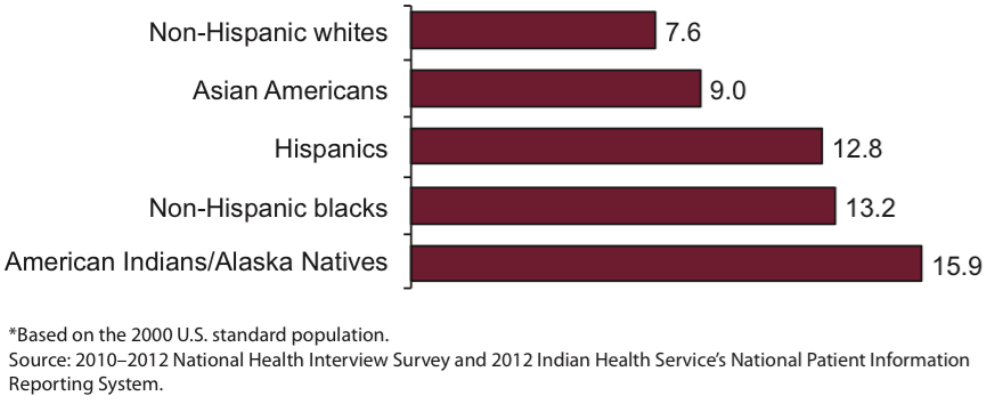
engaging payers and the corresponding payment reforms for medical homes. Therefore, payments tailored to PCMH structures which provide incentives for providers to encourage implementation of the model is an important component of the medical home model.[158] Lastly, although the cost-effectiveness of PCMH for the management of diabetes is not well understood, it has been suggested that interventions are typically most effective, and hence most cost-effective for diabetes patients with the poorest control at baseline and for low-income populations.[27,159]

1.2.7 Diabetes Mellitus in Underserved Populations

It is well documented that the burden of diabetes is higher among minorities and lower-income groups in the US, and this burden in this population has been associated with higher prevalence, worse control and higher complication rates.[8,9] Racial or ethnic minority groups that include African Americans, Hispanics, Asians, Native Hawaiians and Other Pacific Islanders, American Indians and Alaska Natives are more likely than non-Hispanic Whites to be poor and have lower education. These have been linked to cultural and language barriers, uninsured status and poor access to care. The disparities in access and quality of care subsequently lead to higher risk of diabetes complications.[10,11]

Asian Americans have a 1.2 times higher risk of diagnosed diabetes as compared to non-Hispanic Whites while Hispanics and non-Hispanic Blacks both have a 1.7 times higher risk. All other minorities also have a higher percentage of diagnosed diabetes as compared to non-Hispanic Whites (Figure 1.1).[7] It is also common for these populations of patients to seek care in the later stage of the disease, therefore increasing the cost and burden to the health care system.[10] A published review found that children who are uninsured, non-white and from lower-income families are less likely to have medical homes.[69] There is a national urgency to reduce disparities and improve the quality of care in the management of diabetes among vulnerable populations.[11]

Figure 1.1 Racial and ethnic differences in diagnosed diabetes among people aged 20 years or older (2010-2012)



Source: Adapted from "National Diabetes Statistics Report: Estimates of Diabetes and Its Burden in the United States, 2014", Centers for Disease Control and Prevention, 2014, page 2.

Several initiatives have been developed to improve care for underserved populations.[160] One of the widely implemented measures is the integration of health care professionals like nurses, medical assistants and pharmacists with certified diabetes education training in primary care clinics. These efforts have produced positive outcomes in patient empowerment, HbA1c, lipid levels, blood pressure, diabetes related examinations (e.g., eye and foot examinations) and smoking cessation.[8,15,160,161] Many of these initiatives share similarities of having multidisciplinary teams in providing diabetes care.[10,15,160] Trained pharmacists have been valuable in some rural communities with limited physicians. In these areas, patients can receive care without having to travel for health-related education and services.[56]

There are many federal initiatives to diminish health care disparities, particularly in underserved populations with diabetes. These are typically done through CHCs or FQHCs that predominantly serve the needy.[121] Besides that, the Healthy People 2010 stated the aim to strengthen safety nets by increasing the number of CHCs in the US.[162] Other entities like the American Diabetes Association (ADA) has advocated for more diabetes research, treatment, education, and prevention in minority population.[9] There are

various mechanisms by different stakeholders to remedy the disproportionate burden of diabetes among underserved populations. Despite that, the impact of these efforts, as well as national policies on health status of low-income minorities need more examination and effective measures identified should be disseminated better.[8]

1.2.7.1 Integrated Care and Health Outcomes in Underserved Populations

Health care providers, more so the provision of patient-centered care through comprehensive team-based approaches hold the key in overcoming the disparities in underserved populations.[9] PCMHs have been increasingly used as a strategy to tackle this issue in underserved populations. There are published studies that examine PCMH implementation on health outcomes of underserved populations like Alaska Natives, minorities, homeless persons, and uninsured diabetes patients. Several PCMHs have pharmacists on the team and these studies are discussed below.

One PCMH that mainly serves Alaska Natives has been integrating PCMH components since 1999. They report decreases in hospitalizations that are attributed to improved accessibility to the empaneled care teams.[163] In another study, the same team reported overall positive findings on diabetes outcomes after implementing their PCMH and sustaining it for over 14 years. Significant changes include increases in rates of new Type II DM diagnoses and decreases in the number of ED visits. However, there are non-significant results for: increases in rates of HbA1c screening, increases in percent with average HbA1c <7%, and decreases in the number of inpatient days. Despite the varying strength of evidence, data from the time series analysis of this study suggests that positive outcomes from PCMH interventions are sustainable over long periods of time.[12]

Although a full PCMH structure may not have been implemented, other studies have focused on improving diabetes outcomes in underserved populations. One study applied a comprehensive systems-based disease management process including a diabetes registry and an EMR in a community of minority and homeless persons. This study found

significant improvement in quality indicators (percentage of patients having: HbA1c measured, HbA1c <7%, LDL measured annually, LDL <100mg/dL, retinopathy screening, microalbumin test), and suggested that the interventions helped reduce disparities between vulnerable and Caucasian populations.[13]

Regarding the roles of pharmacists in diabetes management of high-risk populations, the American Pharmacists Association (APhA) Foundation has explicitly supported the engagement of pharmacists as integral members of health care teams in populations disproportionately affected by diabetes. Project IMPACT, a multisite observational study was designed specifically to examine the effect of pharmacists integrated to patient-centered, interdisciplinary health care teams, providing customized diabetes education and medication consultations to underserved patients. The pre-post comparison study (n = 1836) conducted in 25 communities across 17 states reported a significant and clinically relevant decrease in mean HbA1c levels (-0.8%, $p < 0.001$). Other clinical outcomes decreased significantly ($p < 0.001$) as compared to the baseline but not by clinically relevant amounts (LDL, –7.1 mg/dL; triglycerides, –23.7 mg/dL; and total cholesterol, –8.8 mg/dL). The mean increase in HDL (+0.6 mg/dL) was not statistically significant or clinically relevant. Additionally, 51.7% of 453 patients with uncontrolled diabetes during the baseline study received eye examinations, 72.0% of 271 patients received foot examinations, 41.7% of 307 patients received influenza vaccinations, and 9.3% of 270 patients quit smoking during the project.[15]

Similar to the IMPACT study, a study based in California compared clinical outcomes of uninsured or underinsured diabetes patients between patients receiving clinical pharmacists (n=222) services and that of usual care (n=262). Comprehensive pharmacy services for vulnerable populations with medical homes in local safety net clinics observed HbA1c levels reduced by 1.38% relative to usual care, increasing the likelihood of achieving an HbA1c <7% by 3-fold ($p<0.001$ for both estimates).[16] Another study described integration of collaborative MTM into a safety net PCMH as a valuable

intervention for homeless patients. This PCMH targets primarily mental health problems and has a pharmacist on the team. The provider acceptance rate for recommendations of identified medication-related problems was high (89%).[103]

Overall, the PCMH approach with pharmacists as essential members has been generating promising results for underserved patients with diabetes. Since much of the economic burden of diabetes is related to its complications, such as blindness, amputation, kidney failure, heart attack, and stroke, the value of these interventions in the management of diabetes in underserved populations with higher risks and burden is even more critical.[9] With that, the paucity of research targeting underserved communities should be addressed and studies that focus on improving the outcomes should be encouraged.[90]

1.2.7.2 Burden of Diabetes Mellitus in Texas and Travis County, and Need for PCMH

According to the latest data from CDC, the age adjusted rate for diagnosed diabetes is 10.9% and the rate of new cases is 9.8 per 1000 for the state of Texas in 2013.[164] The prevalence of diabetes in Texas is estimated to have increased by more than 50% in 10 years, from 2000 to 2010. In 2010, diabetes was among the top ten leading causes of death in Texas, with a mortality rate of 21.7 deaths per 100,000 persons. Regarding hospitalizations, diabetes was the principle reason or was a coexisting condition in 20% of total hospitalizations in Texas, accounting for 27% of total charges for all hospital stays. All of which indicates a high burden of the disease.[165]

Specifically for Travis County, diabetes prevalence was estimated at 9.3% in 2013.[166] Austin is frequently named as one of the fittest cities in the US but disparities are continuously reported for minorities. Death rates and prevalence for diabetes, among other diseases, are persistently higher for African American and Hispanic populations.[167] Overall management of diabetes in Texas is reported to be poorer than the US average, with a higher percentage of patients with uncontrolled HbA1c, LDL, and blood pressure,

and lower rates for HbA1c testing, eye exam, LDL screening, and nephropathy management as compared to the national average.[165]

There are many factors that could explain the high burden of diabetes in Austin and in Texas. First, African Americans and Hispanics or Latinos have higher risks for diabetes, are twice likely to die from diabetes, and are more likely to be obese when compared to whites. The two race groups together, comprise approximately half of the total population in Texas. In Texas, African Americans have the highest prevalence of diabetes as compared to other race groups and the Hispanic population is increasing.[165,168] Moreover, there are associations between higher prevalence of diabetes with lower education and household income levels. In Texas, there are a significantly higher proportion of adults who did not graduate from high school (13.6%), as compared to the US population (10.2%), which may contribute to the differences in diabetes prevalence.[165]

It is apparent that the high burden of diabetes and health inequities due to the social determinants of health need urgent attention. The Austin/Travis County published a recent report that cited the issue of health inequities and emphasized the need for programs that empower patients and eliminate barriers to access care.[167] Provision of high quality primary care via community health centers and PCMHs is a promising strategy that may remedy the disparities issue.[119] Since 2011, support for PCMH for underserved population was shown in Texas when the Texas Health and Human Services Commission (HHSC) encouraged managed care organizations to develop incentive programs for the providers who implement PCMH for Medicaid patients.[169] FQHCs in particular, can be the pioneer in incorporating the PCMH model and demonstrating the effective delivery of primary care in underserved patient populations by improving access to care, with the ultimate goal of reducing and even eliminating health care disparities.[119]

1.2.8 Study Rationale

Although inconclusive, the literature has shown that the impact of integrated care and PCMH on health outcomes has been positive. This suggests that improved models and stronger evidence are needed to support its implementation in the long term. Even though other health care practitioners such as nurses and medical assistants can provide diabetes-specific education, pharmacists are specifically trained in the management of medications, and therefore have a unique position in team-based care.

Furthermore, pharmacists have practice locations in nearly every community throughout the country, rendering them highly accessible. Thus, pharmacists are an ideal provider to deliver needed health care services, especially medication management, to underserved populations.[15] Pharmacists have been gaining recognition in the provision of MTM and clinical services. The growing trust from physicians, other health care providers and society is also reflected with the increasing collaborative practice agreements across the country.[23] Specifically, for the state of Texas collaborative drug therapy management protocol, pharmacists can initiate, modify or continue drug therapy.[152]

The high burden of diabetes, which is even more pronounced in underserved populations, calls for more structured initiatives, such as PCMHs, to overcome this debilitating and resource intense disease state. Most studies involving pharmacist-integrated PCMH with a focus on diabetes management in underserved populations compared clinical outcomes such as HbA1c and LDL, while few studies described the integration and implementation of clinical pharmacist services in PCMHs.

The recent CommUnityCare (FQHCs in Travis County) PCMH transformation and integration of clinical pharmacists into PCMH teams provide an opportunity to investigate these research questions. The description of the PCMH structure and implementation methods may provide valuable information for future integration of

pharmacists into PCMHs and ACOs. Finally, this study may provide more evidence of the value of pharmacists in primary care settings that serve diabetes patients.

1.2.9 Study Aims

To describe the integration of pharmacy services in FQHC PCMHs.

1.2.10 Objectives

The specific objectives of this study are listed as below:

1. To describe and compare the *integration* of clinical pharmacist services in the PCMH and usual care FQHCs, according to the following themes:
    a. PCMH structure and workflow
    b. Roles of pharmacist
    c. Benefits and challenges of PCMH structure
2. To describe the *implementation* of clinical pharmacist services in PCMH FQHCs, according to the Joint Principles of PCMH:
    a. Personal physician
    b. Physician directed medical practice
    c. Whole person orientation
    d. Care is coordinated and/or integrated
    e. Quality and safety
    f. Enhanced access
    g. Payment
3. To qualitatively compare clinical pharmacy services provision between all FQHCs, more specifically on:
    a. Health care professionals involved
    b. Workflow and interprofessional collaborations
    c. Referral and screening of diabetes patients
    d. Implementation of clinical pharmacist services

CHAPTER 2: METHODOLOGY

2.1 STUDY DESIGN OVERVIEW

The objectives of this study, which are to describe integration and implementation of clinical pharmacy services provision in FQHC PCMHs were addressed by conducting semi-structured interviews with four clinical pharmacists in Travis County FQHCs. Three FQHCs with the PCMH model (PCMH group) have pharmacist services provided on the same day of physician visit (co-visit), while one FQHC with usual care (UC group) has pharmacist services provided on separate days, independent of a physician visit.

2.2 INSTITUTIONAL REVIEW BOARD APPROVAL

The Institutional Review Board (IRB) application was submitted to The University of Texas at Austin IRB. Waivers were granted as information required in this research was deemed as non-human subjects.

2.3 STUDY DESIGN

Semi-structured one-on-one qualitative interviews were employed to address the study objectives.

2.4 STUDY INSTRUMENT

A semi-structured interview guide was developed to compare pharmacist-integration in PCMH and usual care models. Semi-structured interviews are useful tools to elicit detailed descriptions of individual experiences and behavior, with the advantages of immediate clarification of ambiguities and probing for further information based on participant responses.[170–172] The questions were designed to investigate the implementation of clinical pharmacy services from the experiences of interviewees providing the services. The interview guide included open-ended questions with the following broad themes: 1) PCMH structure and workflow, 2) roles of pharmacists, and 3) benefits and challenges of PCMH structure. The broad questions are followed-up with

more specific questions on health care professionals involved, pharmacist-physician collaboration, patient selection criteria, clinical pharmacist service provision, documentation, and communication, when appropriate.

The purpose of *PCMH structure and workflow* questions were to better understand: 1) clinical pharmacist implementation approaches adopted by the study sites, 2) referral and screening criteria, 3) patient load, and 4) average patient visit duration. The *roles of pharmacists* questions included the extent and types of clinical pharmacy services provided during co-visits and pharmacist-only visits. The *benefits and challenges of PCMH structure* questions were included to explore the pharmacists' opinions and experiences with the current system. Understanding the exact roles of pharmacists and comparing the differences in service provision may serve as guidance for other FQHCs or other settings who are interested in integrating pharmacists into PCMHs.

2.5 STUDY SITES AND PARTICIPANTS

The study sites were four FQHCs in Austin, Texas, named CommUnityCare. Currently, there are 23 FQHCs in central Texas, including 12 clinics that include pharmacists as an integral part of the health care team. Clinical pharmacists have worked under a collaborative practice agreement with internal medicine physicians since 2005. Under the current collaborative practice agreement, pharmacists have prescriptive authority to initiate and/or adjust diabetes medications, as well as order labs.[173]

Since early 2013, three of the FQHCs (PCMH1, PCMH2, PCMH3) instituted a PCMH model with co-visits, where clinical pharmacist services are provided on the same day as physician visits, with emphasis on interprofessional collaboration. In addition to co-visits in the PCMH FQHCs, pharmacist-only visits were also provided on a scheduled basis, irrespective of when the patient sees the physician. Similarly, in the usual care clinic (UC), pharmacist-only services are also provided irrespective of physician visits. Notably, the usual care clinic uses a disease therapy management usual care model and

does not employ PCMH co-visits. The pharmacist on staff only sees patients with chronic illnesses who are referred by their physician. Patient characteristics (i.e., insurance coverage, demographics) were similar among all four clinics.[173] Purposive sampling was used to recruit the study sample. The study participants are four clinical pharmacists employed by the FQHCs and who agreed to participate in the study.

2.6 DATA COLLECTION AND ANALYSIS

Four face-to-face, one-on-one semi-structured interview sessions were arranged and conducted with clinical pharmacists working in three PCMH FQHCs and one usual care FQHC. The interviews were audio recorded with notetaking by the same interviewer to reduce bias. Qualitative content analysis was conducted independently by two researchers to examine and compare the interview content. Data were categorized and agreement was achieved through discussions.

CHAPTER 3: RESULTS

3.1 CHAPTER OVERVIEW

This chapter presents the results of this study in the order of the interview content themes. The integration of pharmacy services is described and compared among the study sites. Table 3.1 summarizes the main findings from the interviews.

3.2 SEMI-STRUCTURED INTERVIEWS WITH CLINICAL PHARMACISTS

On average, each interview session lasted 45 to 60 minutes. The interview content based on the recorded sessions and notes taken during the interviews are presented below. Specifically, the results are presented according to the structure and workflow of the PCMHs, roles of pharmacists, and benefits and challenges identified from the study sites.

3.3 PCMH STRUCTURE AND PHARMACIST WORKFLOW IN COMMUNITYCARE

Health care professionals involved in PCMH

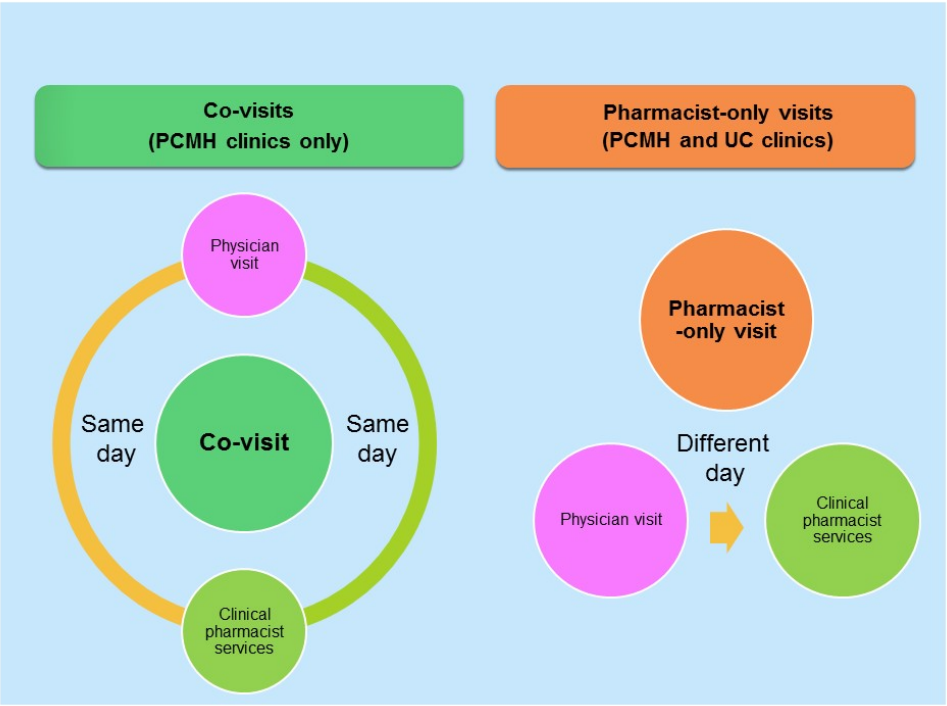
The types of health care professionals are similar for the study clinics in CommUnityCare although the number of health care staff varies by the size of the clinic. Medical assistants, nurse practitioners, nurses and behavioral health counselors are available in all four clinics. Dietitians and social workers are onsite in some locations, but are available to other clinics via referral. The number of physicians ranged from two to five in the study locations and each physician typically has two support staff. Clinics PCMH2 and UC have one clinical pharmacist, while clinics PCMH1 and PCMH3 that are relatively larger and serve more patients have two clinical pharmacists. The estimated number of providers (health care professionals that can prescribe: physicians, nurse practitioners and pharmacists) in PCMH1, PCMH2, PCMH3 and UC are 9, 4, 7 and 5, respectively.

Workflow and interprofessional collaborations

The PCMH workflow involves all healthcare practitioners mentioned above. In the PCMH clinics, medical assistants or nurses take patients' vitals and other important notes electronically prior to physician consultations. The following terms in this study are illustrated in Figure 3.1 and defined as below:

- **Co-visits**: Clinical pharmacist services provided on the same day as physician visit (either before or after), with emphasis on interprofessional collaboration. Co-visits are available in three study clinics (PCMH clinics).
- **Pharmacist-only visits**: "Non co-visit" clinical pharmacist services provided on scheduled basis, irrespective of physician visits (typically on different days). Pharmacist-only visits are available in all four study clinics (PCMH and UC clinics).

Figure 3.1 Co-visits vs Pharmacist-only visits



On co-visit days, the pharmacists may see the patients before or after physician consultation, depending on the physician's schedule. However, the pharmacists in the PCMH clinics reported that most pharmacist visits are conducted before the physician visits. The pharmacists also report this as the preferred workflow because it allows the pharmacists to review the blood glucose readings that physicians typically have limited time to review. When necessary, dietitians and social workers may also see the patient on the same visit day. The main distinction regarding workflow between PCMH and UC clinics is that there are no co-visits in UC, as patients are seen by physicians and pharmacists on separate days.

Clinical pharmacy services for both PCMH and UC clinics are provided according to MTM components and evidence-based medicine, both of which are guided by the collaborative practice agreement. Pharmacists manage the patient by reviewing the medical plan, assessing efficacy, safety and adherence to medications, providing disease state education, and working with the patient to set self-management goals. Pharmacists then document and communicate plans to the prescriber. This entire process is similar for both co-visits (PCMH) and pharmacist-only visits (PCMH and usual care), and it may occur before or after the physician appointment. Thus, interprofessional collaborations are similar.

Referral and screening of diabetes patients

Pharmacy services are provided to diabetes patients who are identified through referral or screening. In all four clinics, referrals vary according to physicians and clinics. Pharmacists typically receive referrals for patients with: uncontrolled diabetes; controlled diabetes, but who may need additional education; or those who are newly diagnosed. Pharmacists may also receive referrals from medical assistants and nurse practitioners. In addition to referrals, pharmacists in two of the PCMH clinics (PCMH1, PCMH2) proactively screen for diabetes patients who may benefit from pharmacist services.

Among the screening criteria are: recent hospitalization, patients who may need dosage adjustment (e.g. due to change in renal function), and needed therapy (e.g. statin, ACE inhibitor). Meanwhile, in the usual care FQHC, pharmacists do not proactively screen for patients: they utilize the referral mechanism for patient visits.

Implementation of clinical pharmacist services

Implementation of co-visits is similar among the three PCMH clinics with each employing fixed co-visit days with open scheduling. Specifically, co-visits are scheduled on two days each week for PCMH1, one day each week for PCMH2, and two mornings each week for PCMH3. The number of patients seen on a co-visit day is highly dependent on the physician's schedule and may range from 0 to 6 for a co-visit session in the morning, or up to 15 patients per co-visit day. The duration of co-visits ranges from 5 to 20 minutes.

For pharmacist-only visits (see Figure 3.1), a scheduling system for clinical pharmacist services in all four clinics allows for up to 12 patient appointments per day, with 30-minute intervals for each appointment. The actual number of patients seen however, may range from 0 to 12 on each pharmacist-only visit day, depending on the number of scheduled pharmacist appointments and patient attendance. For pharmacist-only visits, subsequent patient appointments are typically every four weeks, with exceptions for more urgent cases (e.g. patients who need more frequent insulin titration) where the appointment interval may occur every 2 weeks. For patients who achieve stable control of their diabetes, the follow-up interval for maintenance pharmacist appointments is usually every 3 months, or as needed. While each pharmacist appointment is scheduled for a maximum of 30 minutes, the pharmacists interviewed reported to have consultations lasting from 5 to 30 minutes.

Table 3.1 Provision of pharmacy services integrated in PCMH and usual care clinics

Description	PCMH1	PCMH2	PCMH3	UC
Number of full time pharmacists	2 (+ 1 part time)	1	2	1
Number of co-visit days/week	2	1	2 half days	NA
Average co-visit duration	10 – 15 minutes	5 – 20 minutes	15 – 20 minutes	NA
Average pharmacist-only visit duration	5 – 15 minutes	20 – 30 minutes	30 minutes	15 – 20 minutes
Follow-up appointment interval	Usually every 4 weeks Ranges from 2 weeks – 3 months, depending on urgency and need			
Maintenance appointment for stable patients	Follow-up as needed			
Method to communicate with patients	Typically face-to-face interaction Telephone visits for unique cases			
Pharmacist screen for patients	Yes	Yes	No	No
Number of providers (Physicians, nurse practitioners, pharmacists)	9	4	7	5
Number of diabetes patients*	1500	500	1200	1200

*Estimated number of diabetes patients in 2014

Documentation and communication

Documentation is electronic and all interventions and notes are made in the electronic medical record (EMR). However, communication with the prescriber is mainly through face-to-face interactions during co-visits. The clinical pharmacists usually provide services and interventions independently according to the collaborative practice agreement and inform the prescribers about the changes made. The pharmacists interviewed noted that the physicians are generally receptive and suggestions are commonly accepted. Similarly, clinical pharmacy services are provided through face-to-

face interactions with patients. Telephone interventions are less often utilized and only employed for specific cases, such as to follow-up on home blood glucose readings and for patients who need frequent insulin titrations.

3.4 ROLES OF PHARMACISTS ACCORDING TO THE COLLABORATIVE PRACTICE AGREEMENT

Services provided by the clinical pharmacists during co-visits and pharmacist-only visits are guided by the collaborative practice agreement, which is the same for all clinics. According to the agreement, clinical pharmacists are authorized to prescribe and/or titrate medications, order and interpret laboratory results, order and administer vaccinations, provide disease state education, perform physical assessments, document interventions, and make referrals to other healthcare teams (e.g. dietitians, behavioral health counselors and social workers). These services are available for a number of disease states, including diabetes mellitus, as stated in the agreement. Apart from that, services integral to MTM such as medication reconciliation, adherence assessment and goal setting are also provided. Patients are also educated on basic lifestyle modifications such as exercise and diet. Additionally, some pharmacists take patient vitals during pharmacist-only visits.

When comparing the types of clinical pharmacy services provided during co-visits and pharmacist-only visits, the pharmacists in the PCMH clinics reported that the types of patient education and services are generally similar, although pharmacist-only visits are usually more comprehensive. The pharmacists mentioned that co-visit sessions are often optimized for physician visits by focusing on specific issues, and pharmacists reinforce patient education and other issues during a subsequent pharmacist-only visit. However, for one clinic (PCMH2) with relatively new pharmacist-physician collaborations, the pharmacist provides recommendations to the physician on medications and dosage adjustments during co-visits. Pharmacists in other clinics, where pharmacist-physician

collaborations have been more strongly established, utilize their prescribing and titration privileges (outlined in the collaborative practice agreement) during co-visits.

3.5 BENEFITS AND CHALLENGES OF THE CURRENT STRUCTURE

Benefits of current PCMH structure

Upon interviewing the pharmacists to compare their previous working experience prior to their role in PCMHs, all pharmacists commented that co-visits allow for more collaboration and more efficient communication with physicians. One pharmacist emphasized that in addition to managing the disease condition, pharmacists, being the medication experts, also help in managing the safety component of medication use (e.g. use of metformin in patients who are reaching serum creatinine thresholds) for the medical team. In addition to enhanced team work, pharmacists are appreciated for providing: detailed medication reconciliation, adherence assessment and recommendations to resolve medication-related problems among diabetes patients. Regarding appointment scheduling arrangements for clinical pharmacists, CommUnityCare utilizes an open schedule (a system that accommodates any patient that requires a same-day visit, regardless of a prior appointment) on co-visit days, which allows for patients to receive care when needed. The current structure also allows more convenience and flexibility for patients to see more health care providers on the same day, which is especially helpful for patients that have transportation challenges.

Challenges of current PCMH structure

Despite the advantages of an open schedule for co-visits, pharmacists commented that reserving co-visit days may not be efficient, particularly when they remain unused because no diabetes patients were scheduled for those slots. Therefore an open schedule may not be the most efficient way to optimize clinical pharmacists' time. In contrast, the opposite occurs in clinics with more providers and fewer pharmacists. In a larger clinic (PCMH1) with higher demand for pharmacy services, the number of available pharmacists may not be sufficient to meet the needs of all patients. Consequently,

pharmacists can only see patients selectively, such as patients who are more severe or have more complications. In addition, there are some challenges associated with the physicians as indicated by one pharmacist; some providers believe that pharmacists should see only uncontrolled patients. One pharmacist also mentioned that the current number of social workers and the scope of their services are limited, particularly in clinics that serve primarily underserved populations. Lastly, from the pharmacists' experiences, the barriers associated with diabetes patients in the FQHCs include the lack of education regarding the disease state, poor understanding of diabetes management, patient's self-denial, and social issues which include low literacy, financial barriers and cultural beliefs.

CHAPTER 4: DISCUSSION

4.1 CHAPTER OVERVIEW

This chapter discusses the findings of this study by comparing pharmacist integration to available literature. The implementation of pharmacist services according to the principles of PCMH is also highlighted (see also Table 3.2 for a summary).

4.2 INTEGRATION OF PHARMACY SERVICES

The approach engaged by FQHCs in this study to integrate pharmacists is unique to CommUnityCare clinics. Interestingly, even when the clinics are under the same management, implementation is slightly different among the clinics. These variations reflect the adoption of the principles of PCMHs being **physician-directed** and adapting to meet the specific needs of the patients and clinic.

4.3 PCMH STRUCTURE AND PHARMACIST WORKFLOW IN COMMUNITYCARE

PCMH structure and co-visits

The approach of pharmacist integration in CommUnityCare's PCMH follows the "*employed model*". Full-time pharmacists are employed in the clinic setting to provide direct clinical pharmacy services according to the collaborative practice agreement.[56] The availability of in-house pharmacists at any time fosters teamwork with physicians and other health care professionals.[106] This employed model is usually practical for large group practices or integrated models of care that can afford to hire staff pharmacists.[174] Being imbedded within the clinic also enables pharmacists convenient access to the medical records, which promotes continuity of care.[23,116] CommUnityCare PCMHs employ the "*co-visit model*" where recommendations and modifications are shared with the referring provider on the same day as the patient's physician visit. This same day consult model has also been employed by other PCMHs, although the consultation may be provided by a pharmacist or nurse practitioner in some practices.[107,108] During non co-visit days when pharmacist-only visits are scheduled, care plans are documented between

primary care appointments. The main difference between the PCMH group and usual care group in this study is the availability of co-visits in the PCMH group as opposed to only pharmacist-only visits in the usual care group. Allowing trained pharmacists to optimize drug therapy and provide patient education at the time of a physician visit promotes continuity of care. This may essentially empower the patients and lead to increased adherence, improved self-management skills, and attainment of goals.[146]

Health care professionals involved in PCMH

The variations in the number of staff in the study clinics are unique to each clinic's needs and patient load. Similar to this study, authors described Pennsylvania settings with unique and varied teams of physicians, medical assistants, nurses, nurse practitioners, and office managers in most settings and practice managers, patient information coordinators, and phlebotomists in select settings.[175] Other literature has supported inclusion of behavioral health providers (e.g. psychologists, psychiatrists, social workers, Master's -evel therapists, marriage and family counselors) in PCMHs and other integrated collaborative care settings.[176,177] The need to address mental and behavioral health among primary care patients is particularly important for the underserved population in this study, and is consistent with the emphasis of **whole person orientation**, **coordination** and **continuity of care** of PCMH.[177] The VA has also reported the inclusion of behavioral health providers in their model of integrated care.[178]

Workflow and interprofessional collaborations

According to Smith et al., pharmacist collaboration levels in the present study's PCMH clinics can be categorized as "full collaboration." In this type of collaboration: pharmacists' roles are well defined within the primary care practice workflow; practitioners routinely refer patients to pharmacists; and pharmacists have established collaborative drug therapy management agreements. The usual care clinic (UC), on the other hand, can be categorized as "partial collaboration." In this setting, the pharmacists:

manage medications between physician visits, incorporate clinical pharmacy services in daily huddles; and document patient encounters in the EMRs.

The study sites' organizational structure adheres to the PCMH principle of **personal physician and physician-directed medical practice**.[21] Physicians maintain routine physician appointments with patients while pharmacists provide additional consultations. Furthermore, physicians lead the team of medical professionals in the FQHCs. Also, the collaborative practice agreement states that each patient should have an ongoing relationship with a primary care physician, who is responsible for delegation and supervision of drug therapy management provided by pharmacists. Despite the same collaborative practice agreement and basic structure of PCMH, implementation of pharmacy services differs slightly among the study sites. The provision of integrated clinical pharmacy services, for example, conducting co-visits before or after the physician appointment, depends on the agreement between the pharmacist and physician, as well as the needs of the specific clinic. Similar to another qualitative study,[175] pharmacists in the present study emphasized the importance of being flexible, which facilitates physicians' workflow and allows for more seamless collaboration. Pharmacists noted that most co-visit patients are seen prior to their physician visits. This, together with pharmacist-only visits, which typically occurs between physician visits, allow pharmacists to review patients' charts prior to making recommendations to physicians.[174]

Referral and screening of diabetes patients

The clinics do not have strict referral guidelines. As mentioned previously, referral criteria can include a wide range of patients from those with controlled and uncontrolled diabetes. According to two studies, targeted referrals based on predetermined criteria are more efficient as patients who are more severe can be managed more efficiently.[24,61] Nonetheless, the less stringent approach in the study clinics provide **enhanced access** for patients. It allows for more patients to benefit from pharmacy services, including patients who have clinically controlled diabetes but who may need

additional education on self-management strategies. Pharmacists in two of the PCMH sites (PCMH1 & PCMH2) proactively screen the physicians' daily schedules to determine which patients may benefit from pharmacy services. Identification of post-discharge patients or those who need therapy reflects the **patient-centeredness, team coordination** and **quality and safety** components of the PCMH model. Patients identified through referrals and screenings during co-visits are more easily recruited for further interventions, as compared to referrals for pharmacist appointments on separate days as it can avoid "no-shows" in the latter.

Implementation of clinical pharmacist services

The number of patient visits per half-day clinic reported in this study is similar to that of another PCMH study, where a maximum of 6 patients were seen per session.[35] The frequency and duration of the visits are dependent on the complexity of the individual patient.[174] **Continuity of care** is provided by follow-up visits, which are usually between 2 weeks to 3 months, with the duration of each visit usually not exceeding 30 minutes. This is similar to another study where follow-up appointments occurred every 2 to 6 weeks with appointment duration of 20 to 30 minutes.[107] The same study also mentioned that maintenance appointments for patients who reached goals were scheduled every 3 to 6 months, to prevent "slips" in behavior,[107] as opposed to the current study where patients are scheduled on an 'as needed' basis. Some studies reported longer duration of visits with the pharmacist. For example, a study recorded that the average time spent by a diabetes disease management team led by a clinical pharmacist was about 39 minutes per patient per month, with patient intervention via phone or in person every 2 to 4 weeks.[179] Compared to a PCMH model in Michigan which billed for pharmacist services in 15-minute blocks (telephone visits) and 30-minute blocks (telephone and face-to-face visits),[35] the duration for pharmacist visits with time blocks of 30 minutes in this study is similar.

Documentation and communication

The literature has repeatedly emphasized the importance of communication and efficient utilization of the EMR to facilitate team work and coordination.[48,65] The physical presence of the pharmacists with the prescribing physician on co-visit days facilitates communication and enhances interaction between health care providers. Pharmacists reported good rapport with the physicians in all clinics. Pharmacists indicated that physicians routinely accept their recommendations, which suggests a trusting relationship between pharmacists and providers. This effective communication with physicians and other health care providers either in person or electronically reflects **coordination and integrated care** in the clinics.

Smith et al. indicated that initial patient visits should be face-to-face to build trusted patient-provider relationships, while subsequent follow-up visits can be conducted through a combination of face-to-face visits, telephonic and electronic consultations. In the study sites, all co-visits and most pharmacist visits are conducted in person with the patients and with intermittent telephone calls to follow-up on unique cases. This trend of higher face-to-face visits is similar to a PCMH study with 70% of face-to-face visits.[35]

4.4 ROLES OF PHARMACISTS ACCORDING TO COLLABORATIVE PRACTICE AGREEMENT

Collaborative practice agreements create a formal practice relationship between pharmacists and other providers, defining the range of services that can be provided by pharmacists. Similar to what is implemented in the study clinics, these services often incorporate MTM provision and collaborative drug therapy management, including initiation and modification of drug therapy, ordering and interpretation of laboratory results, as well as physical assessment of the patients.[180] The extensive provision of services by the pharmacists highlights the **whole person orientation and patient-centeredness** as emphasized by the Joint Principles of PCMH.

Currently, at least 46 states have collaborative practice acts.[23] Statutes of collaborative practice agreement vary between states and institutions, with at least 36 states authorizing physician-pharmacist collaborative drug therapy management in any setting.[181,182] In the state of Texas, pharmacists are authorized to modify drug therapy and have prescriptive authority only in specified health facility settings.[182] In this study, although other health care practitioners (e.g. medical assistant, nurse practitioner) may refer patients to the pharmacists, collaborative drug therapy management is authorized only for patients referred by primary care physicians. This again, abides by the principles of **personal physician and physician directed medical practice.**

Other studies have a similar framework and literature on such collaborations is growing.[146,183–185] To illustrate, one interdisciplinary study allowed the clinical pharmacist to initiate, adjust, or discontinue pharmacotherapy and order pertinent laboratory tests and podiatry referrals that are within the scope of the medication management protocol.[185] The agreement of another collaborative practice model for an outpatient cardiovascular pharmacotherapy service however, stated that the roles of pharmacists are to supplement physicians in management of the disease. Therefore, in their model, pharmacists provide recommendations to physicians instead of independent prescribing.[186]

4.5 STRENGTHS AND LIMITATIONS OF CURRENT STRUCTURE

Strengths

Same day access to multiple health care providers provides more opportunities for direct patient-pharmacist-physician interaction and therefore enhances communication. This is viewed as a major advantage as compared to usual care clinics where patients referrals to pharmacists occur during a separate visit. This gap in time may lead to delayed physician response when issues arise.[65,52] Equally important, the open schedule arrangement implemented by CommUnityCare clinics is congruent with the **enhanced access** component of PCMH. This arrangement allows for care to be provided for more

patients who need pharmacist services, including those who may have missed their pharmacist visit if they needed to return to the clinic on a separate day and time.

Pharmacists are well trained in chronic disease management and therefore may be one solution to the current shortage of primary care providers in Texas as well as other states.[182] Successively, through the collaborative practice agreement in PCMHs, more integrated services can be provided to diabetes patients, which may improve access to care, which is especially important for underserved communities.[29,146] Moreover, physicians can have more time for additional patient visits when pharmacists manage complicated patients with complex drug regimens.[174] Such delegation and collaboration is aimed to ultimately reduce utilization of more expensive health care resources such as specialty care and hospitalizations.[29] New models of care for more team based management and the complementary skills of pharmacists place them in a unique position that is increasingly valued.

Limitations

One weakness of the open schedule system in the study PCMH clinics, is that pharmacists have little control over the types of patients who are on the physician's schedule, which occasionally results in no or few co-visits on designated co-visit days. Measures to have diabetes patients on the physician schedule have been discussed with the nurse in charge of one of the clinics to resolve this issue. Likewise, missed pharmacist appointments can be avoided by having support staff send reminders or call patients prior to the pharmacist visit.[24]

Similar to another study, the most recognizable limitation of the current structure is the lack of reimbursement for clinical pharmacy services.[107] **Payment** that recognizes the value of a PCMH is one principle of PCMH that is not fully implemented in the study sites. Pharmacists currently do not bill for their services, although one pharmacist indicated that their clinic plans to do so in the near future. Reimbursement plans for

pharmacist-provided services should be developed, and provider status for pharmacists should be established to fully maximize pharmacists' potential to improve the quality of patient care.[174,182]

Apart from the need for more efficient scheduling system and payment restructuring to improve the current structure, the number of staff such as pharmacists, dietitians and social workers can be optimized to improve interprofessional collaborations in the study clinics. Despite these limitations, the current structure and efforts provide a framework for future implementation of PCMHs. Co-visits may be expanded to other CommUnityCare clinics to improve collaborations and communication between healthcare providers and to improve patient care. On a more general scale, legislative changes for payment restructuring as well as provision of provider status for pharmacists are integral for the further expansion of pharmacists embedment in other PCMHs.

Table 3.2 Summary of pharmacist implementation of the Joint Principles of PCMH

Joint Principles[21]	**Description**[21]	**Implementation involving pharmacists in PCMH**
1. Personal physician	Each patient has an ongoing relationship with a personal physician trained to provide first contact, continuous and comprehensive care.	The patients have routine physician appointments while the pharmacists provide the additional consultations.
2. Physician directed medical practice	The personal physician leads a team of individuals at the practice level who collectively take responsibility for the ongoing care of patients.	Physician leads the team of medical professionals. Primary care physician is responsible for the delegation and supervision of drug therapy management by the pharmacists.
3. Whole person orientation	The personal physician is responsible for providing for all the patient's health care needs or taking responsibility for appropriately arranging care with other qualified professionals.	Pharmacy services incorporate provision of MTM (such as medication reconciliation, adherence assessment and goal setting) and collaborative drug therapy management (authorization to prescribe and/or titrate medications, order and interpret laboratory results, order and administer vaccinations, provide disease state education, perform physical assessments, document interventions, and make referrals to

Table 3.2 continued

		other healthcare team).
4. Care is coordinated and/or integrated	Care is provided across all elements of the complex health care system and the patient's community. Care is facilitated by registries, information technology, health information exchange, and other means to assure that patients get the indicated care when and where they need and want it in a culturally and linguistically appropriate manner.	Pharmacists proactively screen for patients who may benefit from pharmacy services. Pharmacists actively communicate and make referrals to physicians and other health care providers either in person or electronically.
5. Quality and safety	Achieved through patient-centered partnerships, evidence-based medicine, accountability, patients' participation in decision-making, optimal use of information technology, and quality recognition process.	Patients are systematically managed according to evidence-based medicine and are involved in decision-making through goal settings and self-management.
6. Enhanced access	Care is available through systems such as open scheduling, expanded hours and new options for communication between patients, their personal physician, and practice staff.	Flexible referral criteria and open scheduling allow for more patients that need additional education and pharmacy services.
7. Payment	Appropriately recognizes the added value provided to patients who have a patient-centered medical home.	The study sites currently lack of reimbursement for clinical pharmacy services. Arrangements for MTM reimbursement are in progress. Reimbursement plans and provider status for pharmacists should be established to fully maximize pharmacists' potential in improving the quality of patient care.

4.6 STUDY LIMITATIONS

This study has several limitations. First, the qualitative content analysis of the pharmacist interviews may be biased or misrepresented because of researchers' interpretation of pharmacist responses. Second, PCMH implementation varies across sites and may limit the generalizability of the results. The generalizability of the results may be limited to non-FQHCs, patient populations that are not underserved, and practice settings with different collaborative practice agreements or physician-pharmacist relationships. Third, we used a small sample size of four participants in this study that may not represent all FQHCs in Travis County. Nevertheless, the consistency in the responses provided by the participating pharmacists indicate that clinical pharmacist services implementation are similar in the PCMH clinics.

4.7 CONCLUSIONS AND RECOMMENDATIONS FOR FUTURE RESEARCH

The structure of PCMH and the integration of pharmacy services employed by CommUnityCare incorporated the criteria of the Joint Principles of PCMH, namely: personal physician, physician directed medical practice, whole person orientation, care coordination and/or integration, quality and safety, and enhanced access. Efforts are underway to implement a payment structure for pharmacists. PCMH pharmacists in FQHCs were integrated into the workflow to address specific patient needs. Pharmacist and physician visits occurring concurrently (i.e. co-visits) helped to facilitate communication and collaboration when providing care for patients in underserved communities. Strategies for reimbursement are needed to sustain this model of care.

Future research may describe the implementation of PCMH from the perspective of other healthcare professionals, such as physicians and nurses, as well as patients. A qualitative research via a focus group involving other stakeholders other than pharmacists may be useful to explore the interprofessional relationships to improve PCMH structures. Objective outcomes such as clinical, utilization and economic outcomes should also be investigated to determine the effectiveness of pharmacist-integrated PCMHs. Results from quantitative analyses may be used to further evaluate the impact of the PCMH structure in FQHCs and serve as models for future development of ACOs and PCMHs that provide cost effective quality health care.

Appendix A: Semi-structured Interview Guide

Patient-Centered Medical Home (PCMH) Pharmacists

1. How is the PCMH structured in your facility?
    a. Who are the staff involved?
        i. How many physicians, pharmacists, pharmacy technicians, nurses, case managers are involved?
    b. Describe the interprofessional collaborations.
        i. How do the different health care professionals communicate and collaborate regarding the patients' care?
        ii. How is health information technology (e.g., electronic medical record) utilized to facilitate collaborations?
2. How are patients selected for clinical pharmacy services?
    a. Describe the referral/screening criteria?
    b. Is there a patient registry?
    c. How many patients are referred/identified per week/month?
    d. Once patients who achieve their therapeutic goals, how are they continuously monitored?
        i. Are they discharged from follow-up with the clinical pharmacist?
        ii. Are they then followed by their primary care physician?
        iii. Is the follow-up period less frequent?
3. What services do the clinical pharmacists provide?
    a. Will you please share a copy of your collaborative practice agreement?
    b. Please describe to what extent the following services are provided:
        i. Medication reconciliation, initiation, dosage adjustment via collaborative agreement
        ii. Adherence assessment
        iii. Self-management and goal setting
        iv. Patient education on medical condition, nonpharmacologic treatment
        v. Order of laboratory tests
        vi. Referral to others e.g. nutritionist, ophthalmologist, local charities
4. When, specifically, do pharmacists provide clinical services?

a. Are patients seen before, after or during the physician visits? Or is the visit scheduled independently of the physician visit?
b. On average, how much time is spent per patient on new and follow-up visits?
c. Regarding follow-up visits - What is the usual planned frequency?
d. Do you use other methods to provide services besides face-to-face sessions? E.g. telephone, email?
e. Describe the differences in the services provided during a physician co-visit vs. a pharmacy visit?
f. Are tests results reviewed during the co-visit or pharmacy visit? Do you provide point-of-service testing?

5. How do you document and communicate the progress notes? Manual, EMR
    a. How do you communicate with the physician(s)? E.g. EMR, telephone, face-to-face?
    b. How many recommendations/interventions do you perform a day? e.g. dose adjustment, medication change. What is the overall acceptance rate from physicians?
6. Tell me about your experience working in a PCMH setting.
    a. How long have you been working with this facility and providing MTM in this integrated structure?
    b. On average, how many days in a week do you see patients for co-visits and pharmacy visits? And how many patients per day?
    c. Do you provide the services outside of clinic hours? E.g. on weekends, holidays, after clinic hours?
    d. What are the most common problems encountered by diabetes patients? E.g adherence, poor glucose control?
7. What do you view as the benefits/barriers of the current PCMH model?
    a. Patients
    b. Physicians
    c. Other healthcare providers
8. What suggestions do you have to improve the PCMH model?

Usual Care Pharmacists

1. How do healthcare professionals collaborate in your facility?
    a. Who are the staff involved?
        i. How many physicians, pharmacists, pharmacy technicians, nurses, case managers are involved?
    b. Describe the interprofessional collaborations.
        i. How do the different health care professionals communicate and collaborate regarding the patients' care?
        ii. How is health information technology (e.g., electronic medical record) utilized to facilitate collaborations?
2. How are patients selected for clinical pharmacy services?
    a. Describe the referral/screening criteria?
    b. Is there a patient registry?
    c. How many patients are referred/identified per week/month?
    d. Once patients who achieve their therapeutic goals, how are they continuously monitored?
        i. Are they discharged from follow-up with the clinical pharmacist?
        ii. Are they then followed by their primary care physician?
        iii. Is the follow-up period less frequent?
3. What services do the clinical pharmacists provide?
    a. Will you please share a copy of your collaborative practice agreement?
    b. Please describe to what extent the following services are provided:
        i. Medication reconciliation, initiation, dosage adjustment via collaborative agreement
        ii. Adherence assessment
        iii. Self-management and goal setting
        iv. Patient education on medical condition, nonpharmacologic treatment
        v. Order of laboratory tests
        vi. Referral to others e.g. nutritionist, ophthalmologist, local charities
4. When, specifically, do pharmacists provide clinical services?
    a. Are patients seen before, after or during the physician visits? Or is the visit scheduled independently of the physician visit?
    b. On average, how much time is spent per patient on new and follow-up visits?

    c. Regarding follow-up visits - What is the usual planned frequency?
    d. Do you use other methods to provide services besides face-to-face sessions? E.g. telephone, email?
    e. Describe the differences in the services provided during a physician co-visit vs. a pharmacy visit?
    f. Are tests results reviewed during the co-visit or pharmacy visit? Do you provide point-of-service testing?
5. How do you document and communicate the progress notes? Manual, EMR
    a. How do you communicate with the physician(s)? E.g. EMR, telephone, face-to-face?
    b. How many recommendations/interventions do you perform a day? e.g. dose adjustment, medication change. What is the overall acceptance rate from physicians?
6. Tell me about your experience working as a clinical pharmacist.
    a. How long have you been working with this facility and providing MTM?
    b. On average, how many days in a week do you see patients for co-visits and pharmacy visits? And how many patients per day?
    c. Do you provide the services outside of clinic hours? E.g. on weekends, holidays, after clinic hours?
    d. What are the most common problems encountered by diabetes patients? E.g adherence, poor glucose control?
7. What do you view as the benefits/barriers of the current structure and clinical pharmacy services?
    a. Patients
    b. Physicians
    c. Other healthcare providers
8. What suggestions do you have to improve the current structure?

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